UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 29, 2006

Chembio Diagnostics, Inc.
(Exact name of registrant as specified in its charter)

Nevada	333-85787	88-0425691
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

3661 Horseblock Road, Medford, NY 11763
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code (631) 924-1135

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

[ ] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

[ ] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

[ ] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

[ ] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

ITEM 1.01. Entry into a Material Definitive Agreement

On September 29, 2006, the Registrant entered into the material agreements described below.

HIV Barrel License, Marketing and Distribution Agreement

This agreement is a three way agreement among Chembio Diagnostic Systems, Inc. (“Chembio”), Inverness Medical Innovations, Inc. (“Inverness”) and StatSure Diagnostic Systems, Inc. (“StatSure”). This agreement covers Chembio’s FDA-approved SURE CHECK(R) HIV 1/2 (“SURE CHECK”), a lateral flow rapid HIV test employing a proprietary barrel system that is a convenient, safe, accurate and integrated single-use rapid HIV antibody detection screening test. Some terms of the agreement are:

- Inverness will market the SURE CHECK product under Inverness brands globally [subject only to certain existing international agreements Chembio and StatSure may keep in place for up to one year].
- Inverness will exclusively market SURE CHECK under the agreement as well as any new HIV products in the “barrel field” that are developed, and may not compete with

any products in this field worldwide as defined.

- Chembio and StatSure have each granted Inverness exclusive rights to their intellectual property in the HIV barrel field
- Inverness has a first right to negotiate any agreements to market and distribute any new Chembio HIV antibody detection tests, including products that may incorporate Chembio's patent-pending Dual Path Platform (DPP(TM))

HIV Cassette License, Marketing and Distribution Agreement

This agreement is between Chembio and Inverness. This agreement covers Chembio's FDA-approved STAT-PAK(TM) HIV 1/2 ("STAT-PAK"), a lateral flow rapid HIV test employing a cassette system that is a convenient, safe, accurate and a single-use rapid HIV antibody detection screening test. Some terms of the agreement are:

- Inverness will market this product in the US market only; Chembio has a non-exclusive license under the Inverness lateral flow patents to continue to market the product under Chembio's brand in the rest of the world
- Inverness may bring a competitive HIV cassette product to the US market, but in that event Chembio would expand its lateral flow license for this product to the US and have other options under the agreement.

Non-Exclusive License, Marketing and Distribution Agreement

This agreement is between Chembio and Inverness. This agreement covers Chembio's FDA-approved STAT-PAK(TM) HIV 1/2 ("STAT-PAK"), a lateral flow rapid HIV test employing a cassette system that is a convenient, safe, accurate and a single-use rapid HIV antibody detection screening test. Some terms of the agreement are:

- Chembio has received a non-exclusive license under the Inverness lateral flow patents for its HIV 1/2 Dipstick for marketing outside the United States
- Chembio has also received a worldwide non-exclusive license to manufacture and market a number of other Chembio-branded products including all Chembio's rapid tests for human and veterinary and tuberculosis, Chagas disease, and tests for other defined emerging and neglected diseases.
- Inverness has the right to market each of these products (except the HIV 1/2 STAT PAK Dipstick) under an Inverness brand pursuant to an agreed-upon pricing and margin sharing formula similar to the other agreements.

General to the three Agreements above

The agreements with Inverness contain margin sharing formulae that are designed to provide Inverness, Chembio and StatSure with reasonable profit margins after deduction for certain unit costs of the products. Based on their Joint HIV Barrel Product Commercialization Agreement, outlined below, StatSure and Chembio will share 50-50 in the net sales to Inverness of SURE CHECK after these deductions. Chembio will receive all of the net selling price to Inverness in the Cassette Agreement.

Chembio has the exclusive right and duty to manufacture the products marketed by Inverness under all the agreements, and it has the right to subcontract manufacturing, but not sublicense or subcontract its rights or obligations.

Joint HIV Barrel Product Commercialization Agreement and Settlement Agreement with StatSure

Chembio and StatSure have entered into a Settlement Agreement pursuant to which all matters in their litigation regarding StatSure' barrel patent and other matters have been settled. As stated in the second preceding paragraph above, the Joint JIV Barrel Product Commercialization Agreement provides that the parties will equally share in the profits relating to SURE CHECK after reimbursement to Chembio of its manufacturing and related costs, as defined, and that they will act jointly in the HIV barrel field. The settlement combines each company's HIV barrel intellectual property, including an exclusive manufacturing license from StatSure to Chembio of its barrel patent for all HIV applications, thereby ensuring Chembio's exclusive right to manufacture, as well as Inverness' right to market though the marketing license StatSure grants Inverness under the 3-way Agreement.

ITEM 7.01. REGULATION FD DISCLOSURES

(a) On October 5, 2006 the Registrant issued the press release titled "Inverness Medical Innovations, Chembio Diagnostics, Inc. and StatSure Diagnostic Systems, Inc. Announce Agreements to Market Rapid HIV and Other Tests" included herein as Exhibit 99.1.

(b) On October 5, 2006 the Registrant issued the press release titled "StatSure and Chembio Agree to End Litigation and Enter Agreement to Commercialize HIV Barrel Technology" included herein as Exhibit 99.2.

ITEM 8.01 OTHER EVENTS

Also on September 29, 2006, Inverness Medical Innovations, Inc. participated in a private placement of securities of Chembio. See Press Release filed as Exhibit 99.1 and Item 3.02 to a separate form 8-K filed with the U.S. Securities and Exchange Commission on October 5, 2006 by Chembio.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits

10.1 HIV Barrel License, Marketing and Distribution Agreement, dated as of September 29, 2006, by and among the Registrant, Inverness and StatSure.

10.2 HIV Cassette License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Inverness.

10.3 Non-Exclusive License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Inverness.

10.4 Joint HIV Barrel Product Commercialization Agreement, dated as of September 29, 2006, between the Registrant and StatSure.

10.5 Settlement Agreement, dated September 29, 2006, between the Registrant and StatSure.

99.1 Press Release titled "Inverness Medical Innovations, Chembio Diagnostics, Inc. and StatSure Diagnostic Systems, Inc. Announce Agreements to Market Rapid HIV and Other Tests" issued October 5, 2006

99.2 Press Release titled "StatSure and Chembio Agree to End Litigation and Enter Agreement to Commercialize HIV Barrel Technology" issued October 5, 2006

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: October 5, 2006 CHEMBIO DIAGNOSTICS, INC.

By: /s/ Lawrence A. Siebert
Lawrence A. Siebert
Chief Executive Officer

Execution Version

HIV Barrel License, Marketing and Distribution Agreement

Dated As Of

September 29, 2006

Among

Inverness Medical Innovations, Inc.

And

Chembio Diagnostic Systems, Inc.

And

StatSure Diagnostic Systems, Inc.

Table of Contents

HIV Barrel License, Marketing and Distribution Agreement

PREAMBLE

This HIV Barrel License, Manufacturing and Distribution Agreement (the "**Agreement**") is made as of September 29, 2006 ("**Effective Date**"), between and among **Chembio Diagnostic Systems, Inc.**, a **Delaware** corporation having its principal place of business at 3661 Horseblock Road, Medford, New York 11763, ("**Chembio**"), **StatSure Diagnostic Systems, Inc.**, a Delaware corporation having its principal place of business at One Clarks Hill, Framingham, MA 01702 ("**SDS**"), and **Inverness Medical Innovations, Inc.**, a Delaware corporation having its principal place of business at 51 Sawyer Road, Waltham, MA 02453 ("**Inverness**").

RECITALS

Certain capitalized terms used in these Recitals but not defined in the Preamble or upon first use are defined in Section 1.1.

Inverness, among other activities, is in the business of developing, marketing and selling products used to diagnose various diseases, including HIV, and owns or has the right to grant licenses to a number of patents pertaining to HIV diagnosis, including the Inverness Lateral Flow Patents. Inverness asserts that the HIV Barrel Product is within the scope of the claims of the Inverness Lateral Flow Patents.

Chembio, among other things, is in the business of developing, marketing and selling products used to diagnose various diseases, including HIV, and has designed, developed or is in the process of developing the HIV Products (as herein defined) and has received approval of its pre-market application to the FDA for the HIV Barrel Product for manufacture by Chembio at its facility in Medford, New York and for Chembio to market to clinical laboratories and hospitals in the United States.

SDS, among other activities, is in the business of developing, manufacturing and marketing medical diagnostic products and owns the SDS Patents.

During the Term, Inverness wishes to be the exclusive worldwide marketer and distributor of the HIV Barrel Product and license the Inverness Lateral Flow Patents to Chembio for the purpose of manufacturing the HIV Barrel Product for sale by Inverness, and Chembio wishes to obtain such licenses to the extent such licenses are necessary.

During the Term, Chembio also wishes to grant Inverness an exclusive worldwide license to market and sell the HIV Products, to the extent such license is required and, except as provided herein, to covenant not to manufacture the HIV Products for or sell the HIV Products to any Person other than Inverness in the applicable territory and Inverness wishes to obtain such license subject to such covenant.

During the Term, SDS wishes to license the SDS Patents to Inverness on an exclusive basis for the sole purpose of allowing it to market and sell, to the extent such license is required, the HIV Barrel Product manufactured by Chembio exclusively for sale to Inverness and, except as otherwise provided herein, to covenant not to manufacture or sell products that compete with the HIV Barrel Product for diagnosis or detection of HIV infection for or to any Person and Inverness wishes to obtain such license subject to such covenant.

The Parties also intend to enter into such other ancillary agreements, licenses and covenants as may be appropriate to permit the parties to fulfill the business objectives of this Agreement, including, but not limited to, a Joint Exploitation Agreement between SDS and Chembio pursuant to which SDS will grant a license to Chembio to manufacture HIV Barrel Products.

NOW, THEREFORE, in consideration of the premises and the mutual promises, covenants and conditions hereinafter set forth, the receipt and adequacy of which are hereby acknowledged, Chembio, SDS and Inverness hereby agree as follows:

1. **Definitions**.

1.1. **Certain Definitions**

. For purposes of this Agreement, in addition to the terms that are defined on first use herein, the following terms shall have the following meanings:

(a) The "**Act**" shall mean the Federal Food, Drug and Cosmetic Act, as amended, and all relevant federal regulations pertaining thereto.

(b) "**Affiliate**" shall mean any Person that controls, is controlled by, or is under common control with a Party hereto. For purposes of this definition, "control" shall mean (i) in the case of corporate entities, direct or indirect ownership of a majority of the stock or shares having the right to vote for the election of directors, and (ii) in the case of non-corporate entities, direct or indirect ownership of a majority of the equity interest with the power to direct the management and policies of such non-corporate entities.

(c) **"Audit"** shall mean examination of each and every document relating to the licenses and rights granted herein, including but not limited to books, records, agreements, communications, shipping records, purchase orders, invoices, credit memos and record of payments received or made, such audit to be conducted by a nationally recognized public accounting firm.

(d) "**Barrel Field**" means diagnostic testing for the presence of HIV antibodies utilizing an integrated in-vitro diagnostic testing device that (i) is a single use disposable device (ii) collects a physiologic sample from a patient directly into the device and delivers that sample into a system contained in the device, where the reaction reagent medium (for example, a reagent strip) is enclosed in a barrel or other container with a transparent portion which allows the results of the reaction to be visible, designed to protect the user from contact with its contents, (iii) produces a visually readable result in less than 20 minutes, and (iv) is primarily designed to be used in a Point of Care environment or for self-testing by consumers.

(e) "**Challenge**" means, with respect to Patent Rights, to challenge the validity or enforceability of any Patent Rights, including without limitation by (i) filing a declaratory judgment action in which Patent Rights are alleged to be invalid or unenforceable; (ii) citing prior art pursuant to 35 U.S.C. Sec. 301, making a request for re-examination of Patent Rights pursuant to 35 U.S.C. Sec. 302 and/or 311, or provoking or becoming party to an interference with an application for Patent Rights pursuant to 35 U.S.C. Sec. 135; or (iii) filing or commencing any opposition, cancellation, nullity or similar proceedings against Patent Rights in any country.

(f) "**Chembio IP**" shall mean all proprietary rights and Intellectual Property Rights, including but not limited to Patent Rights, owned or Controlled by Chembio, which are necessary or useful for, or would be infringed by, the use, sale, distribution, import or export of the HIV Products, whether now in existence or in the future, including but not limited to those as listed on Schedule A.

(g) "**Chembio Listed Patent**s" shall mean the patents and patent applications listed on Schedule A.

(h) "**Confidential Information**" shall mean all Technology and ideas and information of any kind, whether in written, oral, graphical, machine-readable or other form, whether or not marked or identified as confidential or proprietary, which are transferred, disclosed or made available by any Party hereto to any other.

(i) **"Control"** or **"Controlled by"** shall mean, in the context of Patent Rights or other Intellectual Property Rights, possession of the ability on the part of a Party to grant access to or a license or sublicense as provided for herein without violating the terms of any agreement or other arrangement with any Third Party (other than an Affiliate) existing at the time such Party would be required hereunder to grant another Party such access or license or sublicense.

(j) **"Costs"** shall mean Chembio's costs, calculated in accordance with GAAP and attributed on a per-unit-of-HIV Product basis, of manufacturing and shipping the HIV Products provided to Inverness hereunder, obtaining and maintaining regulatory approvals for the HIV Products to the extent set forth in Section 6.2, and obtaining and maintaining licenses from any Third Parties to manufacture, market, distribute or sell the HIV Products and the amortization over the period during which HIV Products are sold to Inverness of the cost in procuring such licenses. The term "Costs" shall also include costs associated with (1) compliance, (2) complaint handling and (3) quality control. Such costs shall be restricted to costs incurred by Chembio after the Effective Date, except that license fees paid for those licenses listed in Schedule C obtained prior to the Effective Date will be amortized as set forth in Schedule C over the period during which HIV Products are sold to Inverness.

(k) "**Developing Countries**" shall mean those countries listed on Schedule O.

(l) "**Distributor**" shall mean any Third Party, other than an Affiliate of Inverness, to which Inverness grants a limited sublicense under the rights granted Inverness under Section 2.2 and 2.3 for the purpose of reselling or distributing HIV Products.

(m) "**Dual Path Platform**" shall mean Chembio's technology as described in Schedule D.

(n) "**Exploit**" or "**Exploitation**" shall mean to sell, offer for sale, import, export, transport, register, distribute, promote and market, together with other activities typically associated with maximizing the market penetration, profit margins and commercialization of a diagnostic medical product that is marketed to hospitals and clinical laboratories for professional use and to doctors' offices, insurance companies, military facilities, and other Point of Care clinics, as well as to the public for self testing.

(o) "**FDA**" means the U.S. Food and Drug Administration.

(p) "**First Commercial Sale**" shall mean, with respect to a product, the first sale to any non-Affiliate.

(q) "**GAAP**" means United States Generally Accepted Accounting Principles, as applicable to the Party in question.

(r) "**GMP**" means current Good Manufacturing Practices as promulgated by the FDA.

(s) "**HIV Barrel Product**" means the product for HIV testing known as SURE CHECK(R) HIV 1/2 as described in Chembio's PMA on file with the FDA and further described in the SURE CHECK(R) HIV 1/2 package insert, Catalog #HIV202, attached hereto as Schedule E, together with any improvements thereto.

(t) "**HIV Cassette Product**" means the Chembio product currently known as HIV 1/2 STAT PAK(TM) as described in Chembio's PMA on file with the FDA and further described in the HIV 1/2 STAT PAK(TM) package insert, Catalog #HIV 102, which is the subject of a Related Document.

(u) "**HIV Products**" means only any or all of the HIV Barrel Product and New HIV Barrel Product(s).

(v) "**Intellectual Property Rights**" shall mean (i) Patent Rights; (ii) rights associated with works of authorship including copyrights, copyright applications and copyright registrations; and (iii) rights relating to the protection of trade secrets, know-how and Confidential Information, but shall not include any rights to trade marks, trade names, or other distinctive brand names or logos.

(w) "**Inverness Lateral Flow Patents**" shall mean any Patent Rights in the patents and patent applications identified on Schedule F.

(x) "**Inverness Trademarks**" shall mean the trademarks listed on Schedule G.

(y) **Net Sales**.

(i) "**Net Sales**" shall mean, with respect to any HIV Product, the gross amount received by the seller or its Affiliates or Sublicensees on bona fide sales of such HIV Product to Third Parties, less the following items (to the extent the gross amount received by them otherwise reflects such items): (i) credits and allowances for price adjustment, rejection, recall or return of the HIV Product; (ii) amounts for transportation, insurance, handling or shipping charges; (iii) taxes, duties and other governmental charges levied on or measured by the sale of the HIV Product, but not franchise or income taxes of any kind whatsoever; (iv) quantity and other trade discounts, credits or allowances actually allowed and taken; (v) charge back payments and/or rebates for the HIV Product provided to managed health care organizations, international organizations, or federal, state, local or other governments, including, in the United States, Medicare and Medicaid; or (vi) license fees, royalties or similar amounts paid to Third Parties to allow the seller or its Affiliates or Sublicensees to Exploit the relevant Licensed Product without infringement of Third Party (other than an Affiliate of the seller) Intellectual Property Rights. Net Sales shall not include any consideration received for demonstrations, test marketing, clinical trial purposes or compassionate or similar use. All of the amounts specified in the definition of Net Sales shall be determined from the books and records of seller of the HIV Product, its Affiliates and Sublicensees, maintained in accordance with GAAP, consistently applied.

(ii) **Bundling**. In the event that any particular HIV Product is sold as part of a bundle or kit with products other than the HIV Product, the Net Sales allocated to such HIV Product shall be determined by multiplying the net selling price (that is, the gross selling price less such applicable deductions as are permitted in the calculation of Net Sales) of the bundle or kit by the fraction A ÷ (A + B) where A is the average selling price during the period in question in the country in question in quantities similar to the sale in question for the HIV Product sold separately and B is the average selling price during the period in question in the country in question in quantities similar to the sale in question for the remaining products in the bundle or kit, when such products are sold separately from the HIV Product (in each case as the average selling price is documented by Inverness or its Affiliates or Sublicensees' records). In the event that any products contained in the bundle or kit are not sold separately, the Net Sales from sales of such bundle or kit allocated to HIV Products shall be determined in a fair and equitable manner by mutual agreement of the parties.

(iii) **Sales to Distributors**. It is understood and agreed that all sales of HIV Product by Inverness, its Affiliates and Sub-licensees to any Distributor shall be treated as Net Sales hereunder, and that subsequent sale of HIV Product by any such Distributor shall not be treated as Net Sales hereunder.

(z) "**New HIV Barrel Product**" means the patent pending HIV Barrel Product designed and developed by Chembio which contains absorbent material in the sample collection area and which is further described in Schedule H or any other new product in the Barrel Field for the diagnosis or detection of HIV antibodies.

(aa) "**New Chembio HIV Product**" shall mean any antibody detection assays designed or developed by Chembio that tests for HIV I or HIV II antibodies, including without limitation any HIV test incorporating the Dual Path Platform, but excluding any New HIV Barrel Product.

(bb) "**Party**" or "**Parties**" shall mean each of Inverness, SDS and Chembio (but not their Affiliates).

(cc) "**Patent Costs**" shall mean the costs and expenses paid to outside legal counsel and other Third Parties, allocated in-house costs of legal counsel, and filing and maintenance expenses, incurred in connection with preparing, filing, prosecuting, obtaining and maintaining Patent Rights, including costs and expenses of patent interference, re-examination, reissue, opposition or similar proceedings.

(dd) "**Patent Prosecution Action**" shall mean any and all actions that may be taken in connection with preparing, filing, prosecuting, obtaining and maintaining throughout the world patent protection for Patent Rights licensed hereunder, including patent applications and other related material submissions and correspondence with any patent authorities.

(ee) "**Patent Rights**" shall mean all patents, patent applications and inventions on which patent applications are filed and all patents issuing therefrom worldwide, all disclosures of inventions, together with any extensions, registrations, confirmations, reissues, continuations, divisionals, continuations, continuations-in-part, reexamination certificates, substitutions or renewals, supplemental protection certificates, term extensions (under applicable patent law or other law), provisional rights and certificates of inventions.

(ff) "**Person**" shall mean an individual, corporation, partnership, limited partnership, limited liability company, unincorporated association, trust, joint venture or other organization or entity, including a governmental authority.

(gg) **"POC"** or **"Point of Care"** shall mean an environment where sampling and testing is performed in the presence or near-presence of the patient.

(hh) "**QSRs**" means current Quality Systems Regulations as promulgated by the FDA.

(ii) "**Related Documents**" shall mean the Settlement Agreement and the HIV Barrel Product Commercialization Agreement between SDS and Chembio, the License and Distribution Agreement between SDS and Inverness, the Non-Exclusive License, Marketing and Distribution Agreement between Chembio and Inverness, and the HIV Cassette License, Marketing and Distribution Agreement between Chembio and Inverness.

(jj) "**Rest of the World**" means worldwide, excluding the United States.

(kk) "**SDS Patents**" shall mean all Patent Rights owned or Controlled by SDS that would be infringed, or that SDS asserts would be infringed, by the manufacture, use, sale or import of the HIV Barrel Products, whether in existence now or in the future, including but not limited to those listed in Schedule I.

(ll) "**SDS HIV Cassette Products**" shall mean any Point of Care diagnostic test for HIV antibodies that is outside the Barrel Field and is designed (i) to be read by the naked eye and (ii) primarily to be used in a Point of Care environment.

(mm) **"Specifications"** shall mean the information contained in Schedule E regarding the HIV Barrel Product, together with any and all other related documentation or procedures in possession of Chembio that substantiate or support the information contained within Schedule E.

(nn) "**Sublicensee**" shall mean any sublicensee of any of the rights granted to Inverness under Section 2, other than an Affiliate or a Distributor.

(oo) "**Technology**" shall mean all techniques, inventions, practices, procedures, knowledge, improvements, designs, processes, protocols, compositions, products, methods, works of authorship, know-how, data, clinical data, preclinical data, research and creations (whether or not subject to protection by any Intellectual Property Rights).

(pp) "**Third Party**" shall mean any Person other than Inverness, SDS or Chembio.

(qq) "**United States**" means the United States of America and its territories and possessions, including without limitation Puerto Rico and the U.S. Virgin Islands.

(rr) "**Visual-Read HIV Test**" shall mean a rapid, non-digital diagnostic test for antibodies to HIV designed primarily to be read by the naked eye and to be used in a Point of Care environment. A "Visual-Read HIV Test" expressly excludes digital tests that include a reading device or integrated digital technology to aid in the interpretation or indication of the result.

1.2. **Additional Definitions**

. Certain additional capitalized terms are defined below in the body of this Agreement.

2. **HIV Barrel Product: Exclusive Licenses and Manufacturing and Distribution Arrangements.**

2.1. **Exclusive Right to Manufacture**

. Inverness, on and subject to the terms and conditions contained herein, hereby grants to Chembio and Chembio hereby accepts from Inverness an exclusive worldwide license during the Term under the Inverness Lateral Flow Patents to manufacture the HIV Barrel Product solely for sale to Inverness. Chembio shall manufacture the HIV Barrel Product itself or may subcontract the manufacture of the HIV Barrel Product to the extent permitted by applicable law, but may not sublicense such manufacturing right. If Chembio subcontracts the manufacture of the HIV Barrel Product, Chembio shall enter into a written agreement with such manufacturer consistent with the terms of this Agreement and shall remain primarily liable for breach of this Agreement by the manufacturer.

2.2. **Exclusive Right to Purchase and Exploit**

. Chembio, on and subject to the terms and conditions contained herein, including, without limitation, Section 3(d) hereof, hereby grants to Inverness and Inverness hereby accepts from Chembio the exclusive right to purchase from Chembio and the exclusive right and license under any and all of the Chembio IP to Exploit, throughout the entire world, during the Term, the HIV Barrel Product and may do so utilizing Inverness Trademarks. This right shall be deemed to include a grant to Inverness of the right and license to sell through any Affiliate of Inverness and through Distributors of Inverness or of any Affiliate of Inverness.

(a) Except as provided in Section 2.2(b), 2.2(c), 2.2(d), and 2.2(e), for so long as the right set forth in Section 2.2 above remains exclusive, (i) each of Chembio and SDS shall not, by itself or with one or more Third Parties, manufacture, have manufactured or Exploit any consumable or other device, kit, composition or method that competes with the HIV Barrel Product; and (ii) Chembio shall not, by itself or with one or more Third Parties, manufacture, have manufactured or Exploit any consumable or other device, kit, composition or method that competes with any New Chembio HIV Product for which Inverness is granted the right of Exploitation pursuant to Section 2.2(c). This provision shall not be applicable to the HIV Cassette Product or the SDS HIV Cassette Product, both of which are the subject of a Related Document, nor does this provision restrict either Party in its product development activities.

(b) Inverness agrees that Chembio may engage in research and development efforts pertaining to a New HIV Barrel Product. In the event that Chembio wishes to otherwise Exploit a New HIV Barrel Product, Chembio shall offer to manufacture such New HIV Barrel Product for exclusive sale to Inverness and Inverness may, in its sole discretion, agree to include such New HIV Barrel Product as an HIV Barrel Product subject to this Agreement, in which event such New HIV Barrel Product will be treated as an HIV Barrel Product for all purposes of this Agreement. Chembio understands and agrees that should Inverness reject such inclusion of the New HIV Barrel Product, Chembio shall not Exploit the New HIV Barrel Product during the Term.

(c) In the event that Chembio wishes to Exploit a New Chembio HIV Product, Chembio shall provide Inverness with the first right of refusal on the right to market and distribute the New Chembio HIV Product worldwide. As such, Chembio shall not Exploit any New Chembio HIV Product unless Chembio has first provided Inverness with written notice of its desire to Exploit such Product. Such notice shall be accompanied by information relating to the New Chembio HIV Product reasonably necessary for Inverness to evaluate whether it wishes to market and distribute such product, including a product specification, performance data, and details of the cost and estimated availability for the New Chembio HIV Product. Within thirty (30) days after receipt of such notice, Inverness shall provide Chembio with written notice as to whether it wishes to negotiate marketing and distribution rights for the New Chembio HIV Product; if Inverness fails to provide such notice, Inverness' right of first refusal shall lapse. If Inverness gives such notice, Chembio and Inverness shall negotiate in good faith for a period of at least 90 days (or such longer period as may be agreed in writing) and shall each use reasonable efforts to reach agreement as to the terms on which Inverness may market and distribute such New Chembio HIV Product. In the event that Inverness and Chembio fail to reach agreement by the end of such 90 day period, Chembio may Exploit the New Chembio HIV Product itself, or may enter discussions with any Third Party for the purpose of allowing such Third Party to Exploit such New Chembio HIV Product, provided that Chembio shall not conclude any agreement with a Third Party for the Exploitation of a New Chembio HIV Product on terms that are materially more favorable than the terms offered to Inverness. If Chembio wishes to conclude such an agreement with a Third Party on materially more favorable terms, Chembio shall provide a written copy of such more favorable terms to Inverness. If, within 14 days after receipt of such more favorable terms Inverness provides written acceptance of such terms to Chembio, Chembio shall enter an agreement to Exploit the New Chembio HIV Product with Inverness on the more favorable terms. For the avoidance of doubt, Chembio's right to Exploit the New Chembio HIV Product itself or with a

Third Party pursuant to this paragraph (either because Inverness has allowed its first right of refusal to lapse or because the parties have failed to reach agreement on terms) shall not be construed, in the event that the New Chembio HIV Product infringes the Inverness Lateral Flow Patents, as a license to the Inverness Lateral Flow Patents.

(d) Chembio represents and warrants that: (i) Chembio has previously granted licenses under the Chembio IP to, and/or entered into agreements regarding the HIV Barrel Product with, those companies and for those territories listed in Schedule K (the "Existing Chembio Agreements"); and (ii) complete and accurate copies of the Existing Chembio Agreements are set forth on Schedule K; and (iii) the Existing Chembio Agreements set forth the only licenses or rights Chembio has granted to any Third Party under the Chembio IP or related to the HIV Barrel Product. Subject to the truth of the foregoing representation and warranty, SDS and Inverness acknowledge the existence of the Existing Chembio Agreements. Chembio will use commercially reasonable efforts to terminate the Existing Chembio Agreements at the earliest time permitted thereunder without breach by Chembio.

(e) Inverness agrees that, for a period of up to one (1) year from the Effective Date, Chembio may manufacture the HIV Barrel Product and sell such HIV Barrel Product to Bio-Rad Laboratories, Inc. ("**Bio-Rad**") for Exploitation of such product by Bio-Rad in Mexico, and only Mexico, and accordingly, Inverness hereby grants to Chembio a non-exclusive, royalty-bearing, license, under the Inverness Lateral Flow Patents, solely for the foregoing purpose, for a period of one (1) year from the Effective Date. Such license shall be subject to the payment of royalties by Chembio pursuant to Section 5.6.

2.3. **Exclusive License to SDS Patents**

. SDS, on and subject to the terms and conditions contained herein, including, without limitation, Sections 2.3(a) and 3(d) hereof, hereby grants to Inverness and Inverness hereby accepts a worldwide, exclusive (even with respect to SDS), royalty-bearing license, under any and all SDS Patents, to Exploit the HIV Barrel Products manufactured by Chembio hereunder. For clarity, no license is granted by SDS to Inverness to Exploit in any way any product other than the HIV Barrel Product manufactured by Chembio hereunder.

(a) SDS represents and warrants that (i) SDS has previously granted licenses under the SDS Patents to those companies and for those territories listed in Schedule J (the "**Existing SDS Agreements**"); (ii) complete and accurate copies of the Existing SDS Agreements are set forth on Schedule J; and (iii) the Existing SDS Agreements are the only valid and existing licenses or rights SDS has granted to any Third Party under the SDS Patents that could be used for detection of HIV antibodies. Subject to the truth of the foregoing representation and warranty, Chembio and Inverness acknowledge the existence of the Existing SDS Agreements. SDS will use commercially reasonable efforts to terminate the Existing SDS Agreements at the earliest time permitted thereunder without breach by SDS.

2.4. **Exclusivity an Essential Term**

. Subject to Sections 2.2(d) and 2.3(a) hereof, the foregoing rights and licenses are exclusive to Inverness in connection with marketing, distributing and selling, and exclusive to Chembio in connection with manufacturing, and neither SDS nor Chembio shall utilize or practice, or grant any rights to any Third Party under the SDS Patents (in the case of SDS) or the Chembio IP (in the case of Chembio) in the Barrel Field. Chembio and SDS acknowledge and agree that such exclusivity is of critical importance to Inverness, and that without such exclusivity, Inverness would not have entered into this Agreement.

2.5. **Patent Marking**

. Inverness will include the patent numbers of the SDS Patents and indicate SDS's ownership of such patents on the packaging for all HIV Barrel Products, as set forth in Section 8.4.

2.6. **Treatment of New HIV Barrel Product**

. In the event that Inverness agrees to market a New HIV Barrel Product as an HIV Barrel Product as set forth in Section 2.2(b), SDS shall share in the revenues from such New HIV Barrel Product in accordance with Section 5.3 on the same basis as the sharing of revenues from the HIV Barrel Product, provided that SDS either (i) acknowledges that the New HIV Barrel Product does not constitute an infringement of the SDS Patents, or (ii) agrees to include such New Barrel Product within the license granted to Inverness in Section 2.3 and the license granted to Chembio in the Joint Exploitation Agreement.

2.7. **Inverness Licenses**

. The parties acknowledge that contemporaneously herewith, Inverness is granting to each of SDS and Chembio, pursuant to separate agreements, a license with respect to the exploitation of the Inverness Lateral Flow Patents for certain uses other than HIV Barrel Products. It is understood that SDS and Chembio shall be entitled to receive copies of the agreements entered into by Inverness with the other Party and any amendments as if and when effected.

2.8. **Termination of Licenses Upon Challenge of Validity**

. In all jurisdictions where such agreement is permitted by law, and to the maximum extent so permitted: (a) SDS and Chembio each agrees not to Challenge any Patent Rights of Inverness or its Affiliates in the Inverness Lateral Flow Patents listed on Schedule F; (b) Inverness and Chembio each agrees not to Challenge the Patent Rights in the SDS Patents licensed hereunder, and (c) Inverness and SDS each agrees not to Challenge the Patent Rights in the Chembio Listed Patents. In addition to the foregoing, and whether or not the foregoing prohibition is permissible or otherwise enforceable, in the event that Inverness Challenges any Patent Rights in the SDS Patents licensed hereunder or any Patent Rights in the Chembio Listed Patents, or in the event that either SDS or Chembio Challenge any Patent Right of Inverness or its Affiliates in the Inverness Lateral Flow Patents listed on Schedule F, or SDS Challenges any Patent Rights in the Chembio Listed Patents or Chembio Challenges any Patent Rights in the SDS Patents licensed hereunder, the Party whose right is Challenged shall have the right, in its sole discretion and immediately on written notice to terminate this Agreement for cause. In the event that such termination arises: (a) due to Challenge by Inverness, Section 13.4 shall apply; (b) due to Challenge by Chembio, Section 13.5 shall apply; and (c) due to Challenge by SDS, the license set forth in Section 2.3 shall automatically become perpetual, irrevocable, fully paid-up and royalty free, and SDS shall no longer be entitled to any share of Net Sales of HIV Products pursuant to Section 5.3, which share of Net Sales shall be split equally between Chembio and Inverness. Each Party shall cause its Affiliates to refrain from any Challenge that the Party agrees not to make and the consequences of a Challenge by a Party's Affiliate shall be the same as a Challenge by the Party itself.

3. **Non-Competition; Termination of Exclusivity.**

(a) Subject to Section 3(c), during the Term, Inverness and its Affiliates shall not Exploit any Visual-Read HIV Test that detects antibodies to HIV I and/or HIV II in the Barrel Field. Inverness acknowledges and agrees that the exclusivity resulting from this Section is of critical importance to SDS and Chembio and that without such agreement not to compete, SDS and Chembio would not have entered into this Agreement.

(b) The Inverness covenant not to compete set forth in Section 33 shall not prevent Inverness from licensing any Inverness Lateral Flow Patent to any Third Party for any purpose, nor from manufacturing any diagnostic device outside the Barrel Field on behalf of itself or any Third Party.

(c) The Inverness covenant not to compete set forth in Section 33 shall not prevent Inverness or its Affiliates from competing with any HIV Product by Exploiting any product that is not a Visual-Read HIV Test in the Barrel Field (a "**Permitted Competing Product**"**)**. Without limitation of the foregoing, any Visual-Read HIV Test that does not fall within the Barrel Field, whether or not Exploitation of such Visual-Read HIV Test by a Third Party would infringe the Inverness Lateral Flow Patents, is a Permitted Competing Product. Inverness shall give SDS and Chembio written notice of its intention to Exploit a Permitted Competing Product. Such notice shall be given by Inverness by the later of: (i) **60** days before such Permitted Competing Product is first shipped by Inverness to a US customer or distributor, and (ii) the time that Inverness is first able to give such notice without violation of applicable law, regulation, agreement, or the rules of any securities exchange on which its securities are listed, taking into account that such notice would be Confidential Information of Inverness hereunder. SDS and Chembio specifically acknowledge that nothing in this Agreement shall be construed as limiting Inverness' right to acquire, develop, import, sell and/or manufacture Permitted Competing Products.

(d) At any time after receipt of notice from Inverness pursuant to Section 3(c) or after First Commercial Sale of a Permitted Competing Product, Chembio and SDS may by joint written Non-Exclusivity Notice to Inverness (a "**Non-Exclusivity Notice**"), convert Inverness's exclusive right to distribute the HIV Product into a non-exclusive right. In the event that Chembio and SDS validly exercise their right to issue a Non-Exclusivity Notice, with effect from the giving of such notice Inverness shall grant and agrees to grant to Chembio and SDS a perpetual, non-exclusive, royalty-bearing, worldwide license, under the Inverness Lateral Flow Patents, to manufacture or have manufactured, and Exploit the HIV Product, with royalties of eight and one-half percent (8.5%) of Net Sales in the United States and five percent (5%) of Net Sales in the Rest of the World. This license may not be sublicensed or delegated, but shall be deemed to include a grant to SDS and Chembio of the right and license to sell through any Affiliate of Chembio and/or SDS and through Distributors of Chembio and/or SDS.

(e) Notwithstanding anything in this Section 3 to the contrary, Inverness's continued sales outside the United States of products outside the Barrel Field for which a First Commercial Sale has been made as of the Effective Date of this Agreement, and improvements to such products, that compete with the HIV Products (whether or not they constitute Visual-Read HIV Tests and/or are within the scope of the claims of any of the Inverness Lateral Flow Patents) shall not trigger Inverness's loss of exclusivity hereunder.

(f) For the avoidance of doubt, Inverness may right to acquire, develop, import, sell and/or manufacture any competing product (whether or not a Permitted Competing Product) without loss of its exclusivity pursuant to Section 3(d) if Chembio breaches its obligation to supply Inverness' requirements for HIV Products hereunder, but only during the period that such breach remains uncured.

4. **Limits to Scope of Inverness Licenses**

(a) The parties acknowledge that: (a) the HIV Products may be divided into the "**Existing Products**", meaning the HIV Barrel Product as it exists on the Effective Date, and the "**Future Products**", meaning the New HIV Barrel Product and any modifications to, or future versions of, the HIV Barrel Product or New HIV Barrel Product made after the Effective Date; and (b) the Inverness Lateral Flow Patents may be divided into "**Current Lateral Flow Patents**" and "**Future Lateral Flow Patents**". The "**Current Lateral Flow Patents**" are: (i) the patents and patent applications on Schedule F; (ii) any continuations and divisionals of the patents and patent applications on Schedule F; (iii) any continuations-in-part of the patents and patent applications on Schedule F to the extent the claims thereof are directed to subject matter specifically described in (i) and (ii) above; and (iv) any foreign counterparts of the patents and patent applications described in (i), (ii) and (iii) above. The "**Future Lateral Flow Patents**" means any continuation-in-part of the Current Lateral Flow Patents not described in (iii) above, and any foreign counterpart of such continuation-in-part. All licenses granted by Inverness in this Agreement grant licenses to the Current Lateral Flow Patents with respect to both Existing Products and Future Products. The licenses granted by Inverness in this Agreement grant licenses to Future Lateral Flow Patents: (a) for Existing Products; and (b) for Future Products, but only with respect to claims in the Future Lateral Flow Patents that are infringed by the making, using, selling or importing of any Existing Product. Otherwise, Inverness grants no right or license to any Future Lateral Flow Patents under this Agreement, including without limitation any license to any Future Lateral Flow Patent except as described in the foregoing sentence.

(b) The Parties acknowledge that any licenses to the Inverness Lateral Flow Patents are subject to the limitation that the Charlton Lateral Flow Patents (as described on Schedule F) are not licensed for the Over-The-Counter market; such Charlton Lateral Flow Patents are licensed only with respect to products for sale through any channels for use by licensed professional health-care providers (including hospitals, physicians acting as such and licensed professional health-care centers).

5. **Royalties and Payments.**

5.1. **Exclusive Payment Arrangements**

. This Article 5 describes the manner in which the Parties will share revenues derived from the sale of HIV Barrel Products. Except as otherwise set forth in Section 13.4, no other fees, payments or royalties are due from any Party to any other Party with respect to the licenses and rights set forth in this Agreement.

5.2. **Pricing of HIV Products**

. Subject to the limitations set forth in this Article 5, each Party that sells any HIV Products hereunder may set the prices at which it sells such HIV Products in its sole and absolute discretion.

5.3. **Inverness Sale of HIV Barrel Products - Division of Net Sales**

(a) The Parties shall share Net Sales of HIV Barrel Products in accordance with the formula set forth on Schedule M.

(b) Notwithstanding Schedule M, in no event shall Chembio be required to supply HIV Products where the total return to Chembio and SDS (Costs and profit share) would be less than 115% of Costs, unless all three Parties agree.

(c) Shares of Net Sales will be separately calculated and reported on a quarterly basis, and not on an order-by-order basis.

5.4. **Payments for HIV Products**

. Inverness shall pay Chembio and SDS in accordance with the following procedure:

(a) From the Effective Date until the end of the second full calendar quarter after the Effective Date, the parties agree that the estimated per-unit amount representing Chembio's Costs for HIV Products to be supplied by Chembio to Inverness ("**Deemed Cost**") shall be the amount set forth on Schedule N, and the estimated per-unit amount representing Inverness' Net Sales for HIV Products sold by Inverness ("**Deemed Price**") shall be the amount set forth on Schedule N. For the remainder of the Term, the Deemed Cost and Deemed Price shall be adjusted each quarter based on the actual per-unit Cost of HIV Products, and the actual per-unit Net Sales for HIV Products, in the latest quarter for which actual Costs and Net Sales have been reported pursuant to Section 5.7.

(b) Each shipment of HIV Products by Chembio shall be accompanied by an invoice, in a form reasonably satisfactory to Inverness, for the HIV Products in the shipment at the then-current Deemed Cost (as hereinafter defined). Within thirty (30) days of receipt of a duly issued invoice for HIV Barrel Product shipped by Chembio in accordance with this Agreement, Inverness shall pay, for such HIV Barrel Products: (i) to Chembio the Deemed Cost of such HIV Barrel Products, and any additional amount due to Chembio pursuant to Schedule M, based on the then-current Deemed Cost and Deemed Price; and (ii) to SDS, any amount due to SDS pursuant to Schedule M, based on the then-current Deemed Cost and Deemed Price.

(c) Any adjustments to actual Costs for overpayments or underpayments made by Inverness shall be made pursuant to the quarterly accountings set forth in Section 5.7. For purposes of these calculations, Cost of HIV Product will be matched to sales on a FIFO basis.

5.5. **Payment by Inverness for Samples**

. Provided that actual Costs do not differ unreasonably from the Deemed Cost set forth herein, Inverness shall pay Chembio 110% of the Costs associated with the manufacture by Chembio of HIV Products that are used by Inverness for demonstrations, testing, clinical trials, sample and compassionate or similar use.

5.6. **Royalties Payable by Chembio on Inverness Lateral Flow Patents**

. With respect to sales made by Chembio and its Affiliates pursuant to Sections 2.2(e), 3(d), and 13.4, Chembio shall pay Inverness a royalty of five percent (5%) of Net Sales of HIV Products sold by Chembio and its Affiliates in Developing Countries, and eight and one-half percent (8.5%) of Net Sales of HIV Products sold by Chembio and its Affiliates in the Rest of the World excluding Developing Countries. For the purposes of this paragraph, HIV Products are "sold" in a particular region, such as a Developing Country, when a sale is made to a Distributor that is located in such region; provided, however that Inverness reserves the right to charge the higher royalty rate if it can reasonably show that a Distributor located in a Developing Country is selling HIV Products to a purchaser located in a non-Developing Country and Inverness shall charge the lower royalty rate if Chembio can reasonably demonstrate that its Distributor or purchaser located in a non-Developing Country has purchased goods for sale or distribution in a Developing Country.

(a) No royalties shall be payable unless the HIV Product infringes a Valid Claim of the Inverness Lateral Flow Patents in the country in which the HIV Product is manufactured or the country in which the HIV Product is sold.

(b) Only one royalty shall be due Inverness for any HIV Product regardless of the number of Valid Claims of the Inverness Later al Flow Patents that would be infringed.

(c) The obligation to pay royalties on Net Sales of HIV Product shall be imposed only once with respect to each HIV Product, even if such HIV Product is sold more than once in the course of its transfer to the ultimate end-user.

(d) The above royalties on HIV Products are not payable by Chembio with respect to HIV Products distributed by Inverness, for which the revenue sharing arrangements set forth in Section 5.3 are the sole and exclusive payment arrangements between the parties.

5.7. **Reporting and Calculation of Payments**.

(a) For any calendar quarter for which payments under Section 5.3 are due to Chembio and SDS, Inverness shall deliver to Chembio and SDS, within sixty (60) days after the end of such calendar quarter, reasonably detailed written accountings of Net Sales of the HIV Products during such calendar quarter. Such report shall indicate Net Sales on a country-by-country and HIV Product-by-HIV Product basis (and not on an order-by-order basis).

(b) Within seventy-five (75) days of the end of each calendar quarter during the Term, Chembio shall deliver to Inverness and SDS a complete and accurate accounting of all Costs and a determination of the cost per unit for all HIV Products sold to Inverness pursuant to this Agreement. The Costs reflected shall be the basis for adjustments to payments of Cost to Chembio pursuant to Section 5.4 and the payment of profit shares to Chembio and SDS by Inverness pursuant to Schedule M. The per-unit allocation of Costs to products sold shall be determined on a FIFO basis. Cost so determined shall remain in effect until the next such accounting.

(c) Within ninety (90) days after the end of any calendar quarter for which reports have been delivered pursuant to sub-paragraphs (a) and (b) above, Inverness shall deliver Chembio and SDS a report showing the calculation of the amounts due to Chembio and SDS pursuant to Schedule M, and any payments to be made hereunder. Such payments may be payable from either Inverness, SDS or Chembio, depending on whether Chembio and SDS have been underpaid or overpaid pursuant to the procedure set forth in Section 5.4. The Party due to make such payments shall make them no later than seven days after delivery of such report. With respect to Net Sales invoiced in a currency other than United States Dollars, Net Sales and royalties payable shall be expressed in their United States dollar equivalent, calculated using an average exchange rate for buying United States dollars published by The Wall Street Journal during the calendar quarter. All payments due to any Party hereunder shall be made from the United States in United States dollars by transfer to such bank account as such Party may designate.

(d) For any calendar quarter for which payments are due under Section 13.4(c) to Inverness, the Party owing such payment (the "**Payer**") shall deliver to Inverness (the "**Payee**"), within forty-five (45) days after the end of such calendar quarter, reasonably detailed written accountings of Net Sales of the applicable products during such calendar quarter. Such report shall indicate Net Sales on a country-by-country and HIV Product-by-HIV Product basis, and the calculation of the amounts due to Chembio and SDS pursuant to Schedule M or royalty due to Inverness (if applicable) and payments to be made hereunder, with the amounts due to Chembio pursuant to Schedule M to be reduced by the amounts already paid to Chembio as Deemed Costs of HIV Products pursuant to Section 5.4. When the Payer delivers such accountings, it shall also deliver all payments due under this Agreement to the Payee or Payees for such calendar quarter. With respect to Net Sales invoiced in a currency other than United States Dollars, Net Sales and royalties payable shall be expressed in their United States dollar equivalent, calculated using an average exchange rate for buying United States dollars published by The Wall Street Journal during the calendar quarter. All payments due any Payee hereunder shall be made from the United States in United States dollars by transfer to such bank account as the Payee (as applicable) may designate.

(e) Chembio shall keep complete and accurate records of the latest two (2) years of Costs of HIV Products sold to Inverness hereunder. For the sole purpose of verifying Costs to be reimbursed to Chembio, Inverness and SDS shall have the right once per calendar year to retain an independent certified public accountant, selected by Inverness and SDS and reasonably acceptable to Chembio, to conduct an Audit in the location(s) where such records are maintained upon twenty (20) days prior written notice and during regular business hours, with all information disclosed being deemed Confidential Information hereunder. The cost of the Audit shall be paid by the Party requesting the Audit. Such Audit shall be completed within thirty (30) business days, subject to extension by the auditor if the auditor reasonably determines in good faith that data or information it requires is not available and identifies the data or information required. Results of such review shall be made available to Chembio, SDS and Inverness. Inverness shall recalculate the payments made to the Parties and any Party overpaid shall promptly reimburse any underpaid Party. If a recalculation of Costs is equal to or greater than five (5%) percent of the correctly-calculated Costs, the Party requesting the Audit shall be entitled to have Chembio pay the reasonable out-of-pocket costs incurred by SDS and/or Inverness to retain such independent certified public accountant to conduct such review.

(f) Each Payer shall keep complete and accurate records of the latest two (2) years of sales of HIV Products to which royalties or shares of Net Sales attach hereunder. For the sole purpose of verifying payments due to a Payee, said Payee shall have the right, once per calendar year, to retain an independent certified public accountant, selected by said Payee and reasonably acceptable to the Payer, to conduct an Audit in the location(s) where such records are maintained upon twenty (20) days prior written notice and during regular business hours, with all information disclosed being deemed Confidential Information of the Payer. Such Audit shall be completed within thirty (30) business days, subject to extension by the auditor if the auditor reasonably determines in good faith that data or information it requires is not available and identifies the data or information required. Whichever Party requests the Audit shall bear the costs thereof. Results of such review shall be made available to the Payer and the relevant Payees. If the Audit reflects an underpayment of amounts due, such underpayment shall be promptly remitted to the appropriate Payee by the Payer. If the underpayment is equal to or greater than five (5%) percent of the amount that was otherwise due, the Payee shall be entitled to have the Payer pay the reasonable out-of-pocket costs incurred by the Payee to retain such independent certified public accountant to conduct such review.

(g) Whenever reports upon which payments are based are to be made by any Party, they shall be certified as correct by the Chief Financial Officer of the Party. In addition, to the extent required of a Party by the provisions of the Sarbanes-Oxley Act, each of the Parties shall make available information as may be required for proper certification in accordance with Section 404 and any rules promulgated thereunder.

5.8. **Reimbursable Costs**

. During the term the Parties acknowledge that certain expenses may be incurred for which another Party has expressly assumed responsibility in this Agreement. In such circumstances, the responsible Party shall reimburse the Party that incurs the expenses within thirty (30) days after receipt of an invoice reflecting the amount of the expense incurred. The Parties will use their best efforts to quantify reimbursable expenses before they are incurred.

6. **Regulatory and License Matters**.

6.1. **Facility Registration/Inspections**

. Chembio shall, if it has not done so prior to the Effective Date, register, at its expense, with FDA, in accordance with the Act, each establishment in which it intends to manufacture any HIV Product and maintain, at its expense, all such establishment registrations during the term of this Agreement. Chembio shall permit FDA and Inverness to inspect each such establishment for purposes of verifying Chembio's compliance with the Act, including GMPs and QSRs, and for purposes of verifying that all items being manufactured by Chembio for sale to Inverness hereunder are being manufactured in accordance with the applicable Specifications; Inverness' participation in such inspections shall be at Inverness' cost. Any such inspection by Inverness shall be conducted upon reasonable advance notice to Chembio during the normal business hours of the facility to be inspected. Chembio acknowledges and agrees that no inspection by Inverness pursuant to this Section 6.1 shall relieve or diminish any of Chembio's obligations hereunder.

6.2. **Regulatory Filings**

. The parties agree to share responsibility for (1) obtaining and maintaining, and (2) paying for the obtaining and maintaining of, regulatory approvals required for the lawful distribution and sale of HIV Products in the applicable territories, as follows:

(a) Chembio shall pay for all regulatory approvals in effect as at the Effective Date, including the costs of the CLIA waiver;

(b) Chembio shall use commercially reasonable efforts to obtain, and shall pay for the costs of obtaining and maintaining, ISO 13.485 certification and CE marking for the HIV Products, provided that such costs of CE marking are commercially reasonable;

(c) Inverness shall be responsible for obtaining and maintaining regulatory approvals (to the extent that such approvals have not already been obtained as at the Effective Date) for all countries other than the United States, provided that Chembio and SDS shall cooperate and provide supporting materials for such regulatory approvals as reasonably requested by Inverness, and Chembio and SDS shall bear their own costs of so doing;

(d) the parties specifically acknowledge that they have not reached an agreement herein as to who shall be responsible for OTC regulatory costs, but do agree that they shall negotiate in good faith on the issue of which parties shall be responsible for obtaining and maintaining, and paying for the costs of obtaining and maintaining, regulatory approval for sale of HIV Products in the U.S. over-the-counter market.

6.3. **Authorization for Sales in European Union**

. Inverness, at its expense, with assistance of Chembio, shall use commercially reasonable efforts to prepare and submit an application for regulatory approval to distribute and sell the HIV Barrel Product in the European Union countries. Inverness shall seek similar authorization in the Rest of the World, to the extent Inverness deems such authorization appropriate in its reasonable commercial judgment, for the right to distribute and sell the HIV Barrel Product.

6.4. **Bio-Rad Laboratories, Inc.**

Inverness shall use reasonable commercial efforts to obtain and maintain licenses for any and all intellectual property necessary from Bio-Rad Laboratories Inc. to permit Inverness to Exploit the HIV Products, provided any license fees or royalties payable may be deducted from gross sales pursuant to sub-paragraph (vi) of the definition of "Net Sales" as set forth herein. Inverness is aware of the royalties requested by Bio-Rad Laboratories, Inc. and agrees that it will pay appropriate royalties if a license can be obtained.

7. **Manufacture and Sale**.

7.1 **Chembio Efforts**

. Chembio shall use commercially reasonable efforts to manufacture the HIV Product and to supply all of Inverness' requirements for such product, in accordance with the published specifications for each such HIV Product (the "**Specifications**") and the supply requirements and limitations set forth in this Section 7.

7.2 **Forecasts**

. During the Term, Inverness shall provide Chembio, on a quarterly basis, with forecasts of Inverness's anticipated orders for the HIV Barrel Product during the succeeding three (3) quarters. The initial forecast shall be produced and delivered by Inverness to Chembio by the later of 60 days after the Effective Date or 60 days after the CLIA waiver is obtained. Chembio hereby acknowledges and agrees that Inverness shall have the right to revise any quarterly forecast issued pursuant to this Section at any time upon notice given to Chembio not less than three months before the forecast delivery date for any products; any forecasts for delivery less than three months from the forecast date shall be binding on both parties. Inverness shall issue purchase orders and accept delivery of not less than ninety (90%) percent of the forecast quantity. Chembio shall not be required to timely deliver more than one hundred and twenty-five (125%) percent of the forecast quantity, but shall deliver not less than 100% of the quantity required by Inverness' binding forecasts. Chembio shall forward to SDS a copy of all forecasts received from Inverness within five (5) business days of receipt thereof.

7.3 **Purchase Orders**

. All sales and purchases of the HIV Barrel Product, if any, hereunder shall be initiated pursuant to Inverness's purchase order for the same placed with Chembio. Such purchase orders shall include relevant details of the order such as quantity, the current Costs of each HIV Barrel Product, destination, billing and shipping information, and requested delivery date(s) (a "**Purchase Order**"). Chembio shall accept Purchase Orders by written notice to Inverness within five (5) days of receipt. In the event that Chembio cannot comply with a delivery date requested by Inverness in any Purchase Order, Chembio may request an alternative delivery date, which shall be not more than forty-five (45) days after the date requested by Inverness. Any terms and conditions contained in any Purchase Order or written acceptance of a Purchase Order, invoice or other writing delivered by Chembio to Inverness or by Inverness to Chembio that are inconsistent with the terms and conditions of this Agreement shall be null and void and of no effect unless agreed to in a writing executed by an authorized representative of Inverness and Chembio. At any time up to ten (10) days prior to the delivery date set forth in any Purchase Order, Inverness may issue an alteration to a Purchase Order in order to (i) change a location for delivery, (ii) correct typographical or clerical errors, or (iii) reschedule a delivery. In such event, Inverness shall reimburse Chembio for all reasonable resulting costs incurred by Chembio and notified by Chembio to Inverness within seven (7) days after alteration of the purchase order. Chembio shall forward to SDS a copy of all Purchase Orders or alternatives thereof within five (5) business days of receipt thereof.

7.4 **Shipment Terms**

. HIV Barrel Product ordered by Inverness shall be shipped FOB, point of manufacture, with the carrier and to the destination specified in the Purchase Order.

7.5 **Acceptance**

. Within twenty (20) days after receipt of the HIV Barrel Product, Inverness shall inspect and, in its discretion, test the HIV Barrel Product to determine whether they conform in all material respects to the Specifications. In the event an HIV Product does not so conform, Inverness may within such twenty (20) day period (i) continue to test the HIV Barrel Product, or (ii) return the non-conforming HIV Product and Documentation to Chembio, at Chembio's expense, and any amounts paid by Inverness for the HIV Barrel Product returned shall be refunded by Chembio to Inverness. If Inverness does not return a non-conforming HIV Product within such twenty (20) day period, it is deemed accepted.

7.6 **Sales Effort**

. Inverness shall use commercially reasonable efforts to launch, promote, develop a demand for the HIV Barrel Product, and to Exploit the HIV Barrel Products to the markets for which regulatory approvals have been obtained throughout the applicable territory and perform such responsibilities diligently, with the objective of maximizing the sales potential of those products and promoting the benefits thereof in the most commercially beneficial manner.

7.7 **Inverness Responsibilities; Rights**

. In connection with its responsibilities for distribution, marketing and sales of the HIV Products (as permitted in this Agreement), Inverness shall provide all sales force (including, without limitation, sales administration and training), order entry, customer service, reimbursement management, medical affairs, medical information, marketing (including all advertising and promotional expenditures), warehousing, physical distribution, invoicing, credit and collections, production forecasting and other related facilities and services as it deems necessary or desirable for such distribution, marketing and sales.

7.8 **Marketing Plans and Budgets**

. Inverness shall prepare proposed marketing and promotional plans for each of the HIV Products (as permitted in this Agreement), which shall include plans related to the prelaunch, launch, promotion and sales of the HIV Products and which shall include but not be limited to pricing strategy, sales targets, forecasts for the number of sales representatives, copies of promotional materials and a reasonably descriptive overview of the marketing and advertising campaigns proposed to be conducted (the "Marketing Plans"). Inverness shall review the proposed Marketing Plans with Chembio and SDS as soon as practicable after preparation and as frequently as may be required based upon Inverness' usual marketing campaign cycles, but in no case less that once each calendar year during the Term. Inverness shall consider comments from Chembio and SDS on the Marketing Plans in good faith, but Chembio and SDS shall have no right of approval with respect to such Marketing Plans. Inverness shall meet with Chembio and SDS at their request but no more than on a quarterly basis to discuss sales activity and results in each market segment.

8. **Trademarks**

8.1. **Trademark License**

. Inverness hereby grants Chembio a non-exclusive, non-transferable license to use the Inverness Trademarks, but only for the purpose of labeling and packaging the HIV Products for sale to Inverness. All such use of the Inverness Trademarks shall inure to the benefit of Inverness. Chembio shall not use or alter such marks in a manner which may jeopardize or diminish Inverness's rights to use them, and all notices of rights therein and all notices of any patent and/or patent pending rights to the HIV Products shall be clearly designated in all written materials in which such marks are used.

8.2. **Compliance with Law; Registration**

. Chembio, in using Inverness's trademarks, shall use such marks and/or names only in such manner as will comply with the provisions of applicable trademark laws. Any and all trademark applications which are filed in any jurisdiction for a Party's trademarks shall be filed by that Party and that Party shall bear all costs incurred in connection with such trademark applications and registrations. No trademark costs incurred by Chembio shall be included in Costs.

8.3. **Termination**

. The license granted under Section 8.1 shall terminate upon any termination of this Agreement, and thereafter neither Party shall use the other Party's trade names, service marks, or trademarks except in connection with sale by Inverness of HIV Products purchased prior to the termination of this Agreement.

8.4. **Labeling**

. Inverness shall develop, produce and provide all labeling for the HIV Products, subject to Chembio's and SDS' approval. All materials referring or relating to the HIV Products shall include the following in legible font: "Manufactured by Chembio Diagnostic Systems, Inc., Medford, NY for Inverness Medical Innovations under [patents no.s of SDS Patents] owned by StatSure Diagnostic Systems, Inc. [address] and, if applicable, [patent no.s of Inverness Lateral Flow Patents] owned or licensed by Inverness Medical Innovations, Inc."

9. **Prosecution and Enforcement of Licensed Intellectual Property**.

9.1. **Prosecution**

. The owner of Intellectual Property Rights (the "**Patent Owner**") (for example, Inverness in the case of the Inverness Lateral Flow Patents, Chembio in the case of the Chembio IP and SDS in the case of the SDS Patents) shall have the sole right to prepare, file, prosecute, obtain and maintain throughout the world, and otherwise take all Patent Prosecution Actions with respect to its Intellectual Property Rights as such Patent Owner shall deem to be appropriate in its discretion. Each Patent Owner shall pay all Patent Costs incurred by it in connection with the foregoing activities and such Patent Costs shall not be deemed Costs hereunder. If it becomes necessary or desirable, the other Parties shall fully cooperate with the Patent Owner, at the Patent Owner's request and expense, in connection with all Patent Prosecution Actions; provided that no Party shall be obligated to provide such cooperation if, in its reasonable business judgment, such cooperation would be adverse to its interests outside this Agreement.

9.2. **Enforcement of Licensed Patents**

. The Patent Owner shall have the sole right to enforce and defend any of its Intellectual Property Rights licensed hereunder, at its own expense. Notwithstanding the foregoing, each of the Parties shall inform the other Parties promptly in writing of any alleged infringement, misuse or misappropriation by any Person of any Intellectual Property Rights licensed hereunder that affects the Exploitation of HIV Products or other products licensed hereunder, and the Parties shall reasonably consult with each other with respect to the strategy to resolve the alleged infringement, misuse or misappropriation. In the event that a Patent Owner shall initiate an infringement action or defend an action in accordance with this Section, the other Parties shall fully cooperate and supply such assistance as reasonably requested by the Patent Owner; provided that no Party shall be obligated to provide such cooperation if, in its reasonable business judgment, such cooperation would be adverse to its interests outside this Agreement.

10. **Confidentiality**.

10.1. **Limited Disclosure and Use**

. Each of Inverness, Chembio and SDS shall hold in confidence any Confidential Information disclosed by any other Party or otherwise obtained by such Party from any other as a result of this Agreement, and each of Inverness, SDS and Chembio shall protect the confidentiality thereof with the same degree of care that it exercises with respect to its own information of a like nature, but in no event less than reasonable care. Without the prior written consent of the disclosing Party, a receiving Party shall not use, disclose, or distribute any Confidential Information, in whole or in part, except as required to perform such Party's obligations or exercise such Party's rights hereunder. Access to the disclosing Party's Confidential Information shall be restricted to the receiving Party's employees and agents, who, in each case, need to have access to carry out a permitted use and are bound in writing to maintain the confidentiality of such Confidential Information.

10.2. **Exceptions**

. The obligations set forth in Section 10.1 shall not apply to any portion of the Confidential Information that the receiving Party can demonstrate by legally sufficient evidence: (i) now or hereafter, through no act or failure to act on the part of the receiving Party, is or becomes generally available; (ii) is known to the receiving Party at the time of receiving such Confidential Information and not subject to an obligation of confidentiality to a Third Party; (iii) is hereafter furnished to the receiving Party by a Third Party as a matter of right (and without violating any agreement with the disclosing Party) without restriction on use or disclosure; or (iv) is independently developed by the receiving Party without use of any Confidential Information received from the other Party. In addition, each receiving Party may disclose Confidential Information to the extent such disclosure is reasonably necessary to protect Intellectual Property Rights to which such Party has a license hereunder, to prosecute or defend litigation, to comply with applicable law or regulation, to obtain necessary or desirable regulatory approvals, to respond to a valid order of a court or other governmental body or any political subdivision thereof, or to conduct preclinical or clinical trials, provided that, other than with respect to disclosure for protecting Intellectual Property Rights, the receiving Party shall use reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed.

10.3. **Use of Name; Disclosure of Terms of the Agreement**

. Except as authorized in Section 8 hereof or otherwise required by applicable law, regulation or the rules of any securities exchange on which such Party's securities are listed, no Party shall use the names of the other Parties in any publicity or advertising without the prior written approval of the other Parties, except that any Party may disclose that they have entered into this Agreement. Except as may be required by applicable law, regulation or the rules of any securities exchange on which such Party's securities are listed, no Party shall disclose any terms or conditions of this Agreement without the prior written consent of the other Parties, provided that a Party may disclose such terms and conditions to any Third Party with whom such Party has

entered into or proposes to enter into a business relationship (including any transaction that would result in a permitted assignment in accordance with the terms and conditions of Section 15.11), provided any such Third Party is informed of the confidentiality restrictions herein with respect to such terms and conditions and agrees to abide by such restrictions.

10.4. **Effect of Termination**

. Each Party shall, upon termination of this Agreement, immediately discontinue use of the other's Confidential Information. Within a reasonable time after termination of this Agreement, but in no event later than thirty (30) days thereafter, all materials containing such Confidential Information shall be returned by the receiving Party or (with the disclosing Party's prior written consent) destroyed, provided, however, that each Party may retain copies of Confidential Information in which the Party has a licensed interest that survives termination (e.g., as provided in Section 13.4 through 13.7).

10.5. **Survival**

. The confidentiality obligations set forth in this Section 10 shall survive any termination or expiration of this Agreement in perpetuity .

11. **Representations; Warranties**.

11.1. **Corporate Power**

. Each Party represents to the other Parties that it has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof. Each Party represents to the other that this Agreement constitutes a valid and binding agreement, enforceable against it in accordance with its terms.

11.2. **No Default or Violation**

. Each Party represents and warrants to the other Parties that the execution, delivery and performance of this Agreement does not (i) violate or require any registration, qualification, consent, approval, or filing under, (1) any law, statute, ordinance, rule or regulation, or (2) any judgment, injunction, order, writ or decree of any court, arbitrator, or governmental entity by which such Party or any of its assets or properties may be bound or (ii) except in the case of the Existing SDS Agreements and the Existing Chembio Agreements, conflict with, require any consent, approval, or filing under, result in the breach or termination of any provision of, constitute a default under, result in the acceleration of the performance of any obligations under, result in the vesting or enhancement of any other Person's rights under, or result in the creation of any lien upon any of such Party's properties, assets, or businesses pursuant to (x) its organizing documents or By-Laws or (y) any material indenture, mortgage, deed of trust, license, permit, approval, consent, franchise, lease, contract, or other instrument or agreement to which such Party is a Party or by which such Party or any of such Party's properties or assets is bound.

11.3. **Licensed Intellectual Property**

. Each Party licensing any Intellectual Property Rights (a "**Licensor**") to any other Party hereunder (a "**Licensee**") represents and warrants to each such Licensee that: (a) it has the full right, title and authority to grant to Licensee the licenses granted hereunder; and (b) to the best of the Licensor's knowledge and except as otherwise disclosed to the Licensee, all such licensed Patent Rights existing as of the Effective Date are valid and enforceable, and all patents, if any, issuing on any of the pending patent applications of the Patent Rights existing as of the Effective Date will be valid and enforceable.

11.4. **Regulatory Matters**

. Chembio represents and warrants to Inverness that, at the time when HIV Products are delivered, it will have obtained regulatory approval under the Act which is required to permit Chembio to manufacture the HIV Products and sell the HIV Products to qualified customers in the United States professional market for use by such customers in accordance with and subject to the limitations contained within the information contained within Schedule E hereof and information related to the HIV Products that is listed by the FDA. Chembio represents and warrants that, with respect to the manufacture of the HIV Products, Chembio will comply with the requirements of the Act, and to the best of its knowledge, all other applicable federal and state laws.

11.5. **Product Quality**

. Chembio represents and warrants that:

(a) Each unit of HIV Product sold to Inverness hereunder shall be manufactured in accordance with and shall comply, at the time of delivery to Inverness, in all material respects with the applicable Specifications therefor, shall perform as intended in all material respects, and shall otherwise be free from defects in material and workmanship; and each unit of HIV Product sold to Inverness hereunder will not, at the time of delivery, be adulterated or misbranded within the meaning of the Act or within the meaning of any jurisdiction in which the definitions of misbranding and adulteration are substantially the same as in the Act, nor will any such unit of HIV Product, at the time of delivery to Inverness, be an article which may not, under the Act, be introduced into interstate commerce.

(b) In the event any unit(s) of HIV Product does not conform with a warranty set forth in Section 11.5(a) applicable thereto, Inverness or an Affiliate of Inverness may return such unit(s) of HIV Product within twenty (20 days of its receipt to Chembio and, in the event Inverness or an Affiliate of Inverness does so, Chembio, within thirty (30) days of its receipt of the return, shall either; (a) refund or credit Inverness's account in an amount equal to the purchase price paid by Inverness for such unit(s) of non-conforming HIV Product, as the case may be, plus freight and insurance charges incurred by Inverness and/or its Affiliate incident to the original and return shipment, as documented by Inverness, or (b) replace, without charge, the non-conforming unit(s) of HIV Product, as the case may be, with an equivalent number of like unit(s) HIV Product, as the case may be, conforming with the applicable warranties set forth in Section 11.5(a) and refund or credit Inverness's account in an amount equal to said original and return freight and insurance charges incurred as documented by Inverness. The cost of returned units and freight and insurance charges hereunder shall not be included in Costs.

11.6. **Exclusion of Other Representations and Warranties**

. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NO PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY REPRESENTATIONS OR WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT. NO PARTY WARRANTS THAT THE OTHER PARTIES WILL RECEIVE ANY PARTICULAR AMOUNT, OR ANY, REVENUES OR PROFITS AS A RESULT OF ENTERING INTO THE BUSINESS ARRANGEMENTS DESCRIBED IN THIS AGREEMENT.

12. **Indemnification**

12.1. **By Manufacturers**

. Each Party that manufactures, either directly or through a contract manufacturer, any HIV Product hereunder (a "**Manufacturer**") hereby agrees to indemnify, defend (using counsel selected by the Manufacturer which is reasonably acceptable to the other Parties) and hold harmless the other Parties, their Affiliates and their respective Distributors and customers, from and against any and all liabilities, losses, (exclusive of lost profits) damages, costs and expenses (including, without limitation, reasonable attorneys' fees, court costs, and out-of pocket expenses) suffered or incurred which arise or result from: (i) the material breach of any warranty or representation of the Manufacturer contained in this Agreement; (ii) any Third Party claim of personal injury (including death) or property damage arising in connection with any HIV Product manufactured by or for the Manufacturer; (iii) any material failure by the Manufacturer to perform any of the covenants, agreements or obligations of the Manufacturer contained in this Agreement; or (iv) any Third Party claim alleging that the manufacture, use, sale, offer for sale, import or export of the HIV Products manufactured by or for the Manufacturer infringes the proprietary rights of the Third Party claimant.

12.2. **By Sellers**

. Each seller of any HIV Product hereunder (a "**Seller**") hereby agrees to indemnify, defend (using counsel selected by the Seller which is reasonably acceptable to the other Parties) and hold harmless the other Parties from and against any and all liabilities, losses (exclusive of lost profits), damages, costs, and expenses (including, without limitation, reasonable attorneys' fees, court costs, and out-of pocket expenses) suffered or incurred by the other Parties which arise or result from: (i) the material breach of any warranty or any representation of the Seller contained in this Agreement; (ii) any material failure by the Seller to perform any of its covenants, agreements, or obligations contained in this Agreement; or (iii) the promotion and sale by the Seller or any Affiliate or Distributor of the Seller of any HIV Product, except to the extent covered by the Manufacturer's defense and indemnification obligations under Section 12.1.

12.3. **Notice of Claims**

. Within thirty (30) days after a Person seeking indemnification hereunder (hereinafter the "**Indemnified Party**") has received notice of or has acquired knowledge of any claim by any Person not a Party to this Agreement of the commencement or threatened commencement of any action or proceeding by any Person not a Party to this Agreement ("**third party claim**") or has acquired knowledge of any other claim hereunder against another Party hereto ("**first party claim**") the Indemnified Party shall, if such claim is indemnifiable by the other Party pursuant hereto (hereinafter the "**Indemnifying Party**"), give the Indemnifying Party written notice of such claim and the commencement or threatened commencement of such action or proceeding, if any. Such notice shall state the nature and basis of such claim, and, if ascertainable, the amount thereof. Notwithstanding the foregoing, the failure of the Indemnified Party to give such notice shall not excuse the Indemnifying Party's obligation to indemnify and, in the case of a third party claim, defend the Indemnified Party, except to the extent the Indemnifying Party has suffered damage or prejudice by reason of the Indemnified Party's failure to give or delay in giving such notice. Within ten (10) business days of receipt of any notice issued by the Indemnified Party pursuant to this Section 12.3, the Indemnifying Party shall notify the Indemnified Party whether the Indemnifying Party acknowledges its indemnification obligation and, in the case of a third party claim, its defense obligation with respect to the claim which was the subject of the Indemnified Party's notice or whether it disclaims such obligations. In the event the Indemnifying Party disclaims or fails to timely acknowledge its obligations with respect to any claim by the Indemnified Party relating to any third party claim, the Indemnified Party shall have the right to defend such claim, with counsel of its own selection, and compromise such claim without prejudice to its right to indemnification hereunder. In the event the Indemnifying Party timely acknowledges its obligations hereunder with respect to any third party claim, the Indemnifying Party shall defend the same with counsel in accordance with this Section. Where the Indemnifying Party shall have acknowledged in writing its obligations hereunder with respect to any third party claim, the Indemnified Party may, at its expense, participate in the defense of such third party claim and no such third party claim shall be settled by the Indemnified Party without the prior written consent of the Indemnifying Party which consent shall not be unreasonably withheld or delayed. At any time after the Indemnifying Party acknowledges its obligations hereunder with respect to any third party claim, the Indemnifying Party may request the Indemnified Party to agree in writing to the payment or compromise of such third party claim (provided such payment or compromise has been previously approved in writing by the third party claimant), and, in the event the Indemnifying Party does so, the Indemnified Party shall promptly agree in writing to such settlement, unless such settlement would involve a remedy or remedies, other than the payment of money damages by the Indemnifying Party, to which the Indemnified Party reasonably objects.

12.4. **Disputes**

. In the event any Party to this Agreement makes a claim against another Party under this Section 12 or in any way relating to or arising under this Agreement and further in the event the Party receiving notice of such claim fails to timely acknowledge its obligations hereunder with respect to such claim or disclaims such obligations, the relevant Parties, within forty (40) days of the date of issuance of notice by the Party making such claim, shall meet and attempt to resolve in good faith the dispute between or among the Parties with respect to such claim. If the Parties fail to resolve such dispute within seventy-five (75) days of the date of issuance of notice by the Party making such claim, the Party making such claim may thereafter commence to arbitrate the claim in accordance with the provisions set forth in Section 15.8. Upon resolution of any claim referred to in this Section 12, whether by agreement between the Parties to this Agreement or the rendering of a final arbitration award, the appropriate Party under such agreement or the Party against which the arbitration award is rendered shall, within ten (10) days of such resolution, pay over and deliver to the other Party funds in the amount of any claim as resolved.

13. **Term and Termination**.

13.1. **Term of Agreement**

. Unless otherwise terminated as expressly provided herein, with respect to each HIV Product, the licenses granted and appointments made hereunder shall commence on the Effective Date and continue until May 31, 2016 (the "**Term**"), provided that any perpetual licenses granted herein shall continue for the duration of the Intellectual Property Rights in respect of which such licenses are granted.

13.2. **Material Breach.**

(a) If a Party:

(i) materially breaches this Agreement in a manner which cannot be cured;

(ii) materially breaches this Agreement in a manner that can be cured and such Party has failed to take steps to begin to cure within ninety (90) days following written notice of breach by the Party or Parties affected by the breach or is not diligently pursuing a cure thereafter; or

(iii) is subject to a petition for relief under any bankruptcy legislation, or makes an assignment for the benefit of creditors, or is subject to the appointment of a receiver for all or a substantial part of the Party's assets, and such petition, assignment or appointment, if involuntary, is not dismissed or vacated within ninety (90) days (each an "**Insolvency Event**"),

then, on each such occasion, the non-breaching Party shall have the right to exercise one or more of the following remedies: (x) upon written notice by the non-breaching Party to the breaching Party within thirty (30) days of the end of the applicable cure period (if any) (assuming that the non-breaching Party has not already given such a notice upon the occurrence of a prior material, uncured breach by the breaching Party), the non-breaching Party shall have the right to seek monetary damages for such material breach within the limitations set forth in Section 14 hereof and/or equitable relief to prevent such material breach from continuing or occurring again in the future; and, at its option, the non-breaching Party shall have the right to terminate the rights of the breaching Party hereunder upon written notice to breaching Party; provided, however, that in the event the alleged breaching Party in good faith challenges the allegation of breach, then the matter shall be resolved in accordance with Section 15.8, and the cure period set forth in Section 13.2(a)(ii), which shall be reduced to 30 days, shall only commence upon a decision pursuant to Section 15.8 that such breach has occurred. Notwithstanding the foregoing, if Chembio shall be enjoined from supplying HIV Products to Inverness because of a lawsuit regarding Intellectual Property Rights of a Third Party, or Inverness shall be enjoined from selling HIV Products because of a lawsuit regarding Intellectual Property Rights of a Third Party, and such injunction shall in either case cause a material breach of this Agreement, the non-breaching Party shall not have the right to seek monetary damages for such material breach. Notwithstanding the foregoing, the obligations of the breaching Party, including the licenses granted and appointments made hereunder to the non-breaching Parties shall continue unless both non-breaching Parties agree that such licenses and appointments shall terminate.

(b) In the event of a material breach by Chembio, SDS shall have the right to cure such breach, and Chembio will fully cooperate with SDS, at its own cost, in such cure.

13.3. **Section 365(n); Agreement to Deliver Embodiments**

. All rights and licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11, U.S. Code (the "**Bankruptcy Code**"), licenses of rights to "intellectual property" as defined in the Bankruptcy Code. The Parties agree that the licensee of such rights shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code. Chembio agrees during the term of this Agreement to create and maintain current copies or, if not amenable to copying, detailed descriptions or other appropriate embodiments, of all intellectual property and Technology used in the manufacture of the HIV Products ("**Escrow Materials**"). Chembio hereby grants to Inverness, with effect from the Effective Date, a non-exclusive, royalty-free, perpetual license under the Chembio IP to use the Escrow Materials to Exploit the HIV Products, and, if Chembio fails to supply HIV Products to Inverness as required by this Agreement, to manufacture and have manufactured the HIV Products; provided however that Inverness shall not exercise such license unless Chembio suffers an Insolvency Event. In the event that Inverness obtains the right to manufacture the HIV Products in accordance with this Agreement, Inverness shall be entitled to copies of all Escrow Materials. All rights, powers and remedies of the Inverness provided under this Section 13.3 are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity in the event of any such commencement of a bankruptcy proceeding by or against the Chembio.

13.4. **Effect of Termination for Breach by Inverness**

. Upon any termination made in accordance with Section 13.2(a)(i) or (ii) by SDS or Chembio for breach by Inverness, including without limitation for breach of the non-competition obligation set forth in Section 3:

(a) The license grants contained in Sections 2.2 and 2.3, and the non-compete obligations in Section 2.2(a) and 3, shall terminate;

(b) Inverness may sell any inventory of HIV Products in its possession or control at the effective date of termination, but shall have no further right to Exploit the HIV Products; and

(c) SDS and Chembio shall have a joint perpetual, irrevocable, non-transferable, non-exclusive, worldwide, license under the Inverness Lateral Flow Patents to Exploit the HIV Barrel Product themselves or through agreements with Third Parties, at a royalty of **8.5%** of Net Sales in the United States and **5%** of Net Sales in the Rest of the World, subject to the royalty payment limitations set forth in Section 5.6(a), 5.6(b), and 5.6(c).

13.5. **Effect of Termination for Breach by Chembio**

. Upon any termination made in accordance with Section 13.2(a)(i) and (ii) by Inverness for breach by Chembio:

(a) The license grants contained in Sections 2.2 shall automatically be expanded to permit Inverness to manufacture or have manufactured the HIV Product; such licenses in Section 2.2 (as expanded as set forth in this Section 13.5(a)) shall continue after termination and shall be perpetual and irrevocable, subject always to payment to SDS of its profit share in an amount equivalent to that set forth in Schedule M ((with "Cost" redefined to be Inverness' costs as otherwise set forth in Section 1.1(j), and retention of such Cost by Inverness instead of payment of Cost to Chembio), and to payment to Chembio of royalties on HIV Products at a royalty of 8.5% of Net Sales in the United States and 5% of Net Sales in the Rest of the World; and

(b) Chembio shall, at the written request of Inverness and at no cost to Inverness, provide copies of the Escrow Materials and all other technical information, including all Technology in the Chembio IP, reasonably necessary for Inverness to manufacture, have manufactured and Exploit the HIV Products.

13.6. **Sole Remedy**

. The parties acknowledge that the remedies set forth in Section 13.4 shall be Inverness' sole and exclusive liability, and Chembio's and SDS' sole and exclusive remedy, for any breach of Section 3 by Inverness.

13.7. **Survival**

. No expiration or termination of this Agreement shall affect any rights or liabilities of the Parties which may have accrued prior to the date of expiration or termination. Notwithstanding anything herein to the contrary, upon any expiration or termination of this Agreement, in addition to any provisions that by their terms survive, the provisions of Sections 2.8, 3(d), 5.7, 8.3, 9, 10, 12, 13.3, 13.4, 13.5, 13.6, 14 and 15 shall survive and shall continue in full force and effect in accordance with their respective terms.

14. **Limitation of Liability**.

14.1. **Exclusion of Liability for Certain Damages**

. EXCEPT FOR BREACHES OF ITS CONFIDENTIALITY OBLIGATIONS HEREUNDER AND FOR VIOLATIONS OF ANOTHER PARTY'S INTELLECTUAL PROPERTY RIGHTS AND FOR DAMAGES CAUSED BY A PARTY'S GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT, IN NO EVENT SHALL A PARTY BE LIABLE TO ANY OTHER PARTY FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING, WITHOUT LIMITATION, DAMAGES RESULTING FROM LOSS OF USE, PROFITS, BUSINESS OR GOODWILL, WHETHER OR NOT THE PARTY ALLEGEDLY CAUSING THE DAMAGE HAS BEEN ADVISED OF THE POSSIBILITY THEREOF. THIS SECTION 14 SHALL NOT BE CONSTRUED TO LIMIT ANY PARTY'S INDEMNIFICATION OBLIGATIONS UNDER SECTION 12 HEREOF.

14.2. **Limitation on Liability for Direct Damages**

. EXCEPT FOR BREACHES OF ITS CONFIDENTIALITY OBLIGATIONS HEREUNDER AND FOR VIOLATIONS OF ANOTHER PARTY'S INTELLECTUAL PROPERTY RIGHTS, FOR DAMAGES CAUSED BY A PARTY'S GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT, OR FOR ANY PARTY'S INDEMNIFICATION OBLIGATIONS UNDER

SECTION 12 HEREOF, EACH PARTY'S MAXIMUM AGGREGATE LIABILITY TO ALL OTHER PARTIES OTHER THAN FOR PAYMENTS DUE HEREUNDER SHALL IN NO EVENT EXCEED THE AMOUNT OF $1 MILLION, WHETHER SUCH DAMAGES ARISE IN CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY OR OTHERWISE.

15. **General**.

15.1. **Waivers and Amendments**.

(a) This Agreement may be amended, modified or supplemented only by a written instrument executed by the Parties hereto.

(b) No waiver of any provision of this Agreement, or consent to any departure from the terms hereof, shall be effective unless the same shall be in writing and signed by the Party waiving or consenting thereto. No failure on the part of any Party to exercise, and no delay in exercising, any right or remedy hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such right or remedy by such Party preclude any other or further exercise thereof or the exercise of any other right or remedy. The waiver by any Party hereto of a breach of any provision of this Agreement shall not operate as a waiver of any subsequent breach. All rights and remedies hereunder are cumulative and are in addition to and not exclusive of any other rights and remedies provided by law.

15.2. **Entire Agreement**

. This Agreement, the Schedules hereto and the Related Documents constitute the entire agreement among the Parties hereto with respect to the subject matter hereof and supersede all prior agreements and understandings, whether written or oral, among the Parties, or any of the Parties, in connection with such subject matter.

15.3. **Severability**

. If any provision of this Agreement is found invalid or unenforceable by a court of competent jurisdiction, such provision shall be enforced to the maximum extent permissible by law and the other provisions of this Agreement shall remain in full force and effect.

15.4. **Relationship of the Parties**

. This Agreement shall not constitute any Party the agent or legal representative of any other Party for any purpose whatsoever, and no Party shall hold itself out as an agent of any other Party. This Agreement creates no relationship of joint venturers, partners, associates, employment or principal and agent between or among the Parties, and each of the Parties is acting as an independent contractor. No Party is granted herein any right or authority to, and shall not attempt to, assume or create any obligation or responsibility for or on behalf of any other Party. No Party shall have any authority to bind any other Party to any contract, whether of employment or otherwise, and each Party shall bear all of their respective expenses for its operations, including, without limitation, the compensation of its employees and salespersons and the maintenance of its offices, service and warehouse facilities. Each Party shall each be solely responsible for its own employees and salespersons and for their acts and the things done by them.

15.5. **No Election of Remedies**

. The rights and remedies accorded herein are cumulative and in addition to those provided by law, and may be exercised separately, concurrently, or successively.

15.6. **Notices**

. All notices and other communications hereunder shall be in writing and shall be deemed given if delivered personally, telecopied (with confirmation) or mailed by registered or certified mail (return receipt requested) or delivered by recognized courier service providing evidence of delivery to the Parties at the following addresses:

(a) if to Chembio, to:

Chembio Diagnostic Systems, Inc.
3661 Horseblock Road
Medford, New York 11763

Attention: Lawrence A. Siebert, President
Telecopier No.: (631) 924-6033

with a copy to:

Ruskin Moscou Faltischek, P.C.
1425 Reckson Plaza
15th Floor, East Tower
Uniondale, New York 11556

Attention: Michael L. Faltischek, Esq.,
Telecopier No.: (516) 663-6640

(b) if to SDS, to:

StatSure Diagnostic Systems, Inc.
One Clark's Hill
Framingham, MA 01702
Attention: Chief Executive Officer
Telecopier No.: (508) 872-2728

with a copy to:

Mintz, Levin, Cohn, Ferris,
Glovsky and Popeo, P.C.
One Financial Center
Boston, MA 02111
Attention: Jeffrey M. Wiesen, Esq.
Telecopier No.: 617-542-2241

(c) if to Inverness, to:

Inverness Medical Innovations, Inc.
51 Sawyer Road,
Waltham MA 02454
Attention: General Counsel's office

or at such other address for a Party as shall be specified by like notice.

15.7. **Governing Law**

. This Agreement shall be governed by, and construed and enforced in accordance with, the substantive laws of the State of New York , without giving effect to its conflicts of laws rules.

15.8. **Dispute Resolution**

. In the event of any dispute or disagreement between or among any of the Parties as to the interpretation of any provision of this Agreement or the performance of any obligations hereunder, the matter, upon written request of any Party, shall be referred to mediation and arbitration in accordance with the procedures set forth in Schedule L to this Agreement.

15.9. **Waiver of Jury Trial**

. The Parties each hereby irrevocably and unconditionally waives all rights to trial by jury in any legal action, proceeding or counterclaim with respect to any matter whatsoever arising out of or in connection with or related to this Agreement or the enforcement thereof.

15.10. **Counterparts**

. This Agreement may be executed in two or more counterparts, all of which shall be considered one and the same agreement and shall become effective when two or more counterparts have been signed by each of the Parties and delivered to the other Parties, it being understood that all Parties need not sign the same counterpart. Facsimile execution and delivery of this Agreement by any of the Parties shall be legal, valid and binding execution and delivery of such document for all purposes.

15.11. **Assignment**

. This Agreement is personal to each of the Parties, and no Party shall assign any of its rights or delegate any of its obligations hereunder, including without limitation by operation of law, Change of Control or otherwise, without the prior written consent of the affected other Party or Parties, which consent shall not be unreasonably withheld or delayed, provided, however, that without the consent of the other Parties, Inverness may (i) assign its rights under this Agreement and delegate its obligations hereunder, in whole or in part, to any Person that shall acquire the business of Inverness to which this Agreement relates, or to any Affiliate of such Party, if the assignee shall assume Inverness' obligations hereunder in writing, and (ii) assign this Agreement in connection with a sale or transfer of substantially all of the assets of, or a majority interest in the voting shares of, Inverness or its corporate parent to, or the merger or consolidation of Inverness or its corporate parent with or into, any other Person. In this paragraph, "Change of Control" means any sale of the equity securities of a Party following which the equity holders of such Party immediately prior to such sale own, directly or indirectly, less than 50% of the combined voting power of the outstanding voting securities of such Party, other than in a transaction involving a sale of equity securities for the purpose of raising capital to a group of financial investors in which not less than 50% of such equity securities are purchased by a recognized venture capital or private equity fund or funds and where the management of the selling Party before the financing is substantially the same as the management of such Party after the financing.

15.12. **Force Majeure**

. No Party shall be liable for failure to perform any of its obligations under this Agreement when such failure is due to fire, flood, strikes, labor troubles or other industrial disturbances, legal restriction, riot, insurrection, or any other cause beyond the reasonable ability of the Party affected thereby to foresee and avoid, and without such Party's fault or negligence ("Force Majeure"), provided that any Party claiming the existence of Force Majeure shall give notice to the other parties not more than seven (7) days after the commencement of the event of Force Majeure, and shall use prompt and diligent efforts to mitigate the effects of Force Majeure. In the event that any event of Force Majeure prevents performance for sixty (60) days or more, any other Party may terminate this Agreement on written notice to all parties.

15.13. **Further Assurances**

. Each Party hereto will, upon the request of any other Party and without further consideration, execute and deliver such other instruments, and take such other actions, as such other Party may reasonably request, and at the other Party's expense, to more effectively and efficiently carry out the covenants, licenses and agreements of the Parties set forth in this Agreement and consummate the transactions contemplated by this Agreement. Without limitation of the foregoing, each exclusive licensee of rights granted hereunder shall have the right, at its sole cost and expense, to register, record and otherwise document such exclusive license in any country where there are any pending or issued Patent Rights. Such licensee may require that the other Party execute a "short form" license in order to effect the foregoing registration, recordal or other documentation in any such country, and may record such short form license, but no short form license shall in any way alter or otherwise affect the rights and obligations of the Parties hereunder.

[remainder of this page intentionally left blank]

* * *

IN WITNESS WHEREOF, the Parties have executed, or caused their duly authorized representatives to execute, this Agreement under seal as of the date first written above.

Chembio Diagnostic Systems, Inc.

By:
Title:

StatSure Diagnostic Systems, Inc.

By:
Title:

Inverness Medical Innovations, Inc.

By:
Title:

[Signature page to HIV Barrel Marketing and Distribution Agreement]

Execution Version

HIV Cassette License, Marketing and Distribution Agreement

Dated As Of

September 29, 2006

Between

Inverness Medical Innovations, Inc.

And

Chembio Diagnostic Systems, Inc.

Table of Contents

HIV Cassette License, Marketing and Distribution Agreement

PREAMBLE

This HIV Cassette License, Manufacturing and Distribution Agreement (the "**Agreement**") is made as of September 29, 2006 ("**Effective Date**"), by and between **Chembio Diagnostic Systems, Inc.**, a **Delaware** corporation having its principal place of business at 3661 Horseblock Road, Medford, New York 11763, ("**Chembio**") and **Inverness Medical Innovations, Inc.**, a Delaware corporation having its principal place of business at 51 Sawyer Road, Waltham, MA 02453 ("**Inverness**").

RECITALS

Certain capitalized terms used in these Recitals but not defined in the Preamble or upon first use are defined in Section 1.1.

Inverness, among other activities, is in the business of developing, marketing and selling products used to diagnose various diseases, including HIV, and owns or has rights to grant licenses to a number of patents pertaining to HIV diagnosis, including the Inverness Lateral Flow Patents. Inverness asserts that the HIV Cassette Product is within the scope of the claims of the Inverness Lateral Flow Patents.

Chembio, among other things, is in the business of developing, marketing and selling products used to diagnose various diseases, including HIV, and has designed and developed the HIV Cassette Product, and has received approval of its pre-market application to the FDA for the HIV Cassette Product for manufacture by Chembio at its facility in Medford, New York and for Chembio to market to clinical laboratories and hospitals in the United States.

During the Term, Inverness wishes to be the exclusive United States marketer and distributor of the HIV Cassette Product and to license the Inverness Lateral Flow Patents to Chembio for the purpose of manufacturing the HIV Cassette Product for sale by Inverness in the United States and to allow Chembio to manufacture, market and sell the HIV Cassette Product outside the United States, and Chembio wishes to obtain such licenses to the extent such licenses are necessary.

During the Term, Chembio also wishes to grant Inverness an exclusive United States license to market and sell the HIV Cassette Products, to the extent such license is required and, as provided herein, to covenant not to manufacture the HIV Cassette Products for, or sell the HIV Cassette Products to, any Person other than Inverness in the United States and Inverness wishes to obtain such license subject to such covenant.

The Parties are simultaneously entering into certain other agreements, licenses and covenants, including an agreement between the Parties and StatSure Diagnostic Systems, Inc. ("**SDS**").

NOW, THEREFORE, in consideration of the premises and the mutual promises, covenants and conditions hereinafter set forth, the receipt and adequacy of which are hereby acknowledged, Chembio and Inverness hereby agree as follows:

1. **Definitions**.

1.1. **Certain Definitions**

. For purposes of this Agreement, in addition to the terms that are defined on first use herein, the following terms shall have the following meanings:

(a) The "**Act**" shall mean the Federal Food, Drug and Cosmetic Act, as amended, and all relevant federal regulations pertaining thereto.

(b) "**Affiliate**" shall mean any Person that controls, is controlled by, or is under common control with a Party hereto. For purposes of this definition, "control" shall mean (i) in the case of corporate entities, direct or indirect ownership of a majority of the stock or shares having the right to vote for the election of directors, and (ii) in the case of non-corporate entities, direct or indirect ownership of a majority of the equity interest with the power to direct the management and policies of such non-corporate entities.

(c) **"Audit"** shall mean examination of each and every document relating to the licenses and rights granted herein, including but not limited to books, records, agreements, communications, shipping records, purchase orders, invoices, credit memos and record of payments received or made, such audit to be conducted by a nationally recognized public accounting firm.

(d) "**Barrel Field**" means diagnostic testing for the presence of HIV antibodies utilizing an integrated in-vitro diagnostic testing device that (i) is a single use disposable device (ii) collects a physiologic sample from a patient directly into the device and delivers that sample into a system contained in the device, where the reaction reagent medium (for example, a reagent strip) is enclosed in a barrel or other container with a transparent portion which allows the results of the reaction to be visible, designed to protect the user from contact with its contents, (iii) produces a visually readable result in less than 20 minutes, and (iv) is primarily designed to be used in a Point of Care environment or for self-testing by consumers.

(e) "**Challenge**" means, with respect to Patent Rights, to challenge the validity or enforceability of any Patent Rights, including without limitation by (i) filing a declaratory judgment action in which Patent Rights are alleged to be invalid or unenforceable; (ii) citing prior art pursuant to 35 U.S.C. Sec. 301, making a request for re-examination of Patent Rights pursuant to 35 U.S.C. Sec. 302 and 311, or provoking or becoming party to an interference with an application for Patent Rights pursuant to 35 U.S.C. Sec. 135; or (iii) filing or commencing any opposition, cancellation, nullity or similar proceedings against Patent Rights in any country.

(f) "**Chembio IP**" shall mean all proprietary rights and Intellectual Property Rights, including but not limited to Patent Rights, owned or Controlled by Chembio, which are necessary or useful for, or would be infringed by, the use, sale, distribution, import or export of the HIV Cassette Products, whether now in existence or in the future, including but not limited to those as listed on Schedule A.

(g) "**Chembio Listed Patent**s" shall mean the patents and patent applications listed on Schedule A.

(h) "**Chembio Trademarks**" shall mean the Trademarks listed on Schedule B.

(i) "**Confidential Information**" shall mean all Technology and ideas and information of any kind, whether in written, oral, graphical, machine-readable or other form, whether or not marked or identified as confidential or proprietary, which are transferred, disclosed or made available by any Party hereto to any other.

(j) **"Control"** or **"Controlled by"** shall mean, in the context of Patent Rights or other Intellectual Property Rights, possession of the ability on the part of a Party to grant access to or a license or sublicense as provided for herein without violating the terms of any agreement or other arrangement with any Third Party (other than an Affiliate) existing at the time such Party would be required hereunder to grant another Party such access or license or sublicense.

(k) **"Costs"** shall mean Chembio's costs, calculated in accordance with GAAP and attributed on a per-unit-of-HIV Cassette Product basis, of manufacturing and shipping the HIV Cassette Products provided to Inverness hereunder, obtaining and maintaining regulatory approvals for the HIV Cassette Products to the extent set forth in Section 6.2, and obtaining and maintaining licenses from any Third Parties to manufacture, market, distribute or sell the HIV Cassette Products and the amortization over the period during which HIV Cassette Products are sold to Inverness of the cost in procuring such licenses. The term "Costs" shall also include costs associated with (1) compliance, (2) complaint handling and (3) quality control. Such costs shall be restricted to costs incurred by Chembio after the Effective Date, except that license fees paid for those licenses listed in Schedule C obtained prior to the Effective Date will be amortized as set forth in Schedule C over the period during which HIV Cassette Products are sold to Inverness.

(l) **"Developing Countries"** means those countries listed on Schedule J.

(m) "**Distributor**" shall mean any Third Party, other than an Affiliate of Inverness, to which Inverness or Chembio grants a limited sublicense under the rights granted Inverness under Section 2.2 or granted Chembio under Section 2.3 for the purpose of reselling or distributing HIV Cassette Products.

(n) "**Exploit**" or "**Exploitation**" shall mean to sell, offer for sale, import, export, transport, register, distribute, promote and market, together with other activities typically associated with maximizing the market penetration, profit margins and commercialization of a diagnostic medical product that is marketed to hospitals and clinical laboratories for professional use and to doctors' offices, insurance companies, military facilities, and other Point of Care clinics, as well as to the public for self testing.

(o) "**FDA**" means the U.S. Food and Drug Administration.

(p) "**First Commercial Sale**" shall mean, with respect to a product, the first sale to any non-Affiliate.

(q) "**GAAP**" means United States Generally Accepted Accounting Principles, as applicable to the Party in question.

(r) "**GMP**" means current Good Manufacturing Practices as promulgated by the FDA.

(s) "**HIV Barrel Product**" means the product for HIV testing known as SURE CHECK(R) HIV 1/2 as described in Chembio's PMA on file with the FDA and further described in the SURE CHECK(R) HIV 1/2 package insert, Catalog #HIV202, which is the subject of a Related Document.

(t) "**HIV Cassette Product**" means the Chembio product currently known as HIV 1/2 STAT PAK(TM) as described in Chembio's PMA on file with the FDA and further described in the HIV 1/2 STAT PAK(TM) package insert, Catalog #HIV 102, attached hereto as Schedule E, together with any improvements thereto.

(u) "**Intellectual Property Rights**" shall mean (i) Patent Rights; (ii) rights associated with works of authorship including copyrights, copyright applications and copyright registrations; and (iii) rights relating to the protection of trade secrets, know-how and Confidential Information, but shall not include any rights to trade marks, trade names, or other distinctive brand names or logos.

(v) "**Inverness Lateral Flow Patents**" shall mean any Patent Rights in the patents and patent applications identified on Schedule E.

(w) "**Inverness Trademarks**" are the trademarks listed on Schedule F.

(x) **Net Sales**.

(i) "**Net Sales**" shall mean, with respect to any HIV Cassette Product, the gross amount received by the seller or its Affiliates or Sublicensees on bona fide sales of such HIV Cassette Product to Third Parties, less the following items (to the extent the gross amount received by them otherwise reflects such items): (i) credits and allowances for price adjustment, rejection, recall or return of the HIV Cassette Product; (ii) amounts for transportation, insurance, handling or shipping charges; (iii) taxes, duties and other governmental charges levied on or measured by the sale of the HIV Cassette Product, but not franchise or income taxes of any kind whatsoever; (iv) quantity and other trade discounts, credits or allowances actually allowed and taken; (v) charge back payments and/or rebates for the HIV Cassette Product provided to managed health care organizations, international organizations, or federal, state, local or other governments, including, in the United States, Medicare and Medicaid; or (vi) license fees, royalties or similar amounts paid to Third Parties to allow the seller or its Affiliates or Sublicensees to Exploit the relevant Licensed Product without infringement of Third Party (other than an Affiliate of the seller) Intellectual Property Rights. Net Sales shall not include any consideration received for demonstrations, test marketing, clinical trial purposes or compassionate or similar use. All of the amounts specified in the definition of Net Sales shall be determined from the books and records of seller of the HIV Cassette Product, its Affiliates and Sublicensees, maintained in accordance with GAAP, consistently applied.

(ii) **Bundling**. In the event that any particular HIV Cassette Product is sold as part of a bundle or kit with products other than the HIV Cassette Product, the Net Sales allocated to such HIV Cassette Product shall be determined by multiplying the net selling price (that is, the gross selling price less such applicable deductions as are permitted in the calculation of Net Sales) of the bundle or kit by the fraction A ÷ (A + B) where A is the average selling price during the period in question in the country in question in quantities similar to the sale in question for the HIV Cassette Product sold separately and B is the average selling price during the period in question in the country in question in quantities similar to the sale in question for the remaining products in the bundle or kit, when such products are sold separately from the HIV Cassette Product (in each case as the average sellling price is documented by the seller or its Affiliates or Sublicensees' records). In the event that any products contained in the bundle or kit are not sold separately, the Net Sales from sales of such bundle or kit allocated to HIV Cassette Products shall be determined in a fair and equitable manner by mutual agreement of the parties.

(iii) **Sales to Distributors**. It is understood and agreed that all sales of HIV Cassette Product by the seller, its Affiliates and Sub-licensees to any Distributor shall be treated as Net Sales hereunder, and that subsequent sale of HIV Cassette Product by any such Distributor shall not be treated as Net Sales hereunder.

(y) "**Party**" or "**Parties**" shall mean each of Inverness and Chembio (but not their Affiliates).

(z) "**Patent Costs**" shall mean the costs and expenses paid to outside legal counsel and other Third Parties, allocated in-house costs of legal counsel, and filing and maintenance expenses, incurred in connection with preparing, filing, prosecuting, obtaining and maintaining Patent Rights, including costs and expenses of patent interference, re-examination, reissue, opposition or similar proceedings.

(aa) "**Patent Prosecution Action**" shall mean any and all actions that may be taken in connection with preparing, filing, prosecuting, obtaining and maintaining throughout the world patent protection for Patent Rights licensed hereunder, including patent applications and other related material submissions and correspondence with any patent authorities.

(bb) "**Patent Rights**" shall mean all patents, patent applications and inventions on which patent applications are filed and all patents issuing therefrom worldwide, all disclosures of inventions, together with any extensions, registrations, confirmations, reissues, continuations, divisionals, continuations, continuations-in-part, reexamination certificates, substitutions or renewals, supplemental protection certificates, term extensions (under applicable patent law or other law), provisional rights and certificates of inventions.

(cc) "**Person**" shall mean an individual, corporation, partnership, limited partnership, limited liability company, unincorporated association, trust, joint venture or other organization or entity, including a governmental authority.

(dd) **"POC"** or **"Point of Care"** shall mean an environment where sampling and testing is performed in the presence or near-presence of the patient.

(ee) "**QSRs**" means current Quality Systems Regulations as promulgated by the FDA.

(ff) "**Related Documents**" shall mean the Settlement Agreement and HIV Barrel Product Commercialization Agreement between SDS and Chembio, the License and Distribution Agreement between SDS and Inverness, the Non-Exclusive License, Marketing and Distribution Agreement between Chembio and Inverness, and the HIV Barrel License, Marketing and Distribution Agreement between Chembio and Inverness.

(gg) "**Rest of the World**" means worldwide, excluding the United States.

(hh) **"Specifications"** shall mean the information contained in Schedule D regarding the HIV Cassette Product and the together with any and all other related documentation or procedures in possession by Chembio that substantiate or support the information contained within Schedule E .

(ii) "**Sublicensee**" shall mean any sublicensee of any of the rights granted to Inverness under Section 2.2, other than an Affiliate or a Distributor.

(jj) "**Technology**" shall mean all techniques, inventions, practices, procedures, knowledge, improvements, designs, processes, protocols, compositions, products, methods, works of authorship, know-how, data, clinical data, preclinical data, research and creations (whether or not subject to protection by any Intellectual Property Rights).

(kk) "**Third Party**" shall mean any Person other than Inverness or Chembio.

(ll) "**United States**" means the United States of America and its territories and possessions, including without limitation Puerto Rico and the U.S. Virgin Islands.

(mm) "**Valid Claim**" shall mean a claim of an issued and unexpired patent that has not been permanently revoked, held unenforceable or invalid by a final, nonappealable decision of a court or other governmental agency of competent jurisdiction (the term "final, nonappealable decision" includes decisions that become final through exhaustion of all permissible avenues for rehearing or review by a superior tribunal and decisions that become final through expiration of the time allowable for appeal), or admitted by the patentee to be invalid or unenforceable through reissue, reexamination, disclaimer or otherwise.

(nn) "**Visual-Read HIV Test**" shall mean a rapid, non-digital diagnostic test for antibodies to HIV designed primarily to be read by the naked eye and to be used in a Point of Care environment. A "Visual-Read HIV Test" expressly excludes digital tests that include a reading device or integrated digital technology to aid in the interpretation or indication of the result.

1.2. **Additional Definitions**

. Certain additional capitalized terms are defined below in the body of this Agreement.

2. **HIV Cassette Product: Exclusive Licenses and Manufacturing and Distribution Arrangements.**

2.1. **Exclusive Right to Manufacture for United States Sale**

. Inverness, on and subject to the terms and conditions contained herein, hereby grants to Chembio and Chembio hereby accepts from Inverness an exclusive license during the Term under the Inverness Lateral Flow Patents to manufacture the HIV Cassette Product solely for sale to Inverness pursuant to this Agreement. Chembio shall manufacture the HIV Cassette Product itself or may subcontract the manufacture of the HIV Cassette Product to the extent permitted by applicable law, but may not sublicense such manufacturing right. In the event Chembio subcontracts its manufacturing right, Chembio shall enter a written agreement with such contractor consistent with the terms of this Agreement, and Chembio shall remain primarily liable for performance of this Agreement.

2.2. **Exclusive Right to Purchase and Exploit in the United States**

. Chembio, on and subject to the terms and conditions contained herein, including, without limitation, Section 2.2(b) hereof, hereby grants to Inverness and Inverness hereby accepts from Chembio the exclusive right to purchase from Chembio and the exclusive right and license under any and all of the Chembio IP to Exploit, throughout the United States, during the Term, the

HIV Cassette Product and may do so utilizing Inverness Trademarks. This right shall be deemed to include a grant to Inverness of the right and license to sell through any Affiliate of Inverness and through Distributors of Inverness or of any Affiliate of Inverness.

(a) Subject to Section 2.2(b) hereof, the foregoing rights and licenses are exclusive (even as to Chembio) to Inverness in connection with marketing, distributing and selling in the United States, and Chembio shall not itself Exploit, or grant any rights to any Third Party to Exploit, the HIV Cassette Product in the United States. Chembio acknowledges and agrees that such exclusivity is of critical importance to Inverness, and that without such exclusivity, Inverness would not have entered into this Agreement.

(b) Chembio represents and warrants that Chembio has not as at the Effective Date granted licenses under the Chembio IP with respect to, and/or entered into agreements regarding, the Exploitation of the HIV Cassette Product in the United States.

2.3. **Non-Exclusive License under Inverness Lateral Flow Patents**

. Inverness, on and subject to the terms and conditions contained herein, hereby grants to Chembio and Chembio hereby accepts a non-exclusive, royalty-bearing license during the Term, under the Inverness Lateral Flow Patents, to manufacture and to Exploit the HIV Cassette Products in the Rest of the World. This license: (i) may not be sublicensed or otherwise delegated without Inverness' prior written consent, which consent shall not be unreasonably withheld; (ii) includes the right for Chembio to subcontract the manufacture of the HIV Cassette Product, subject to the provisions of Section 2.1; and (iii) shall be deemed to include a grant to Chembio of the right and license to sell through any Affiliate of Chembio and through Distributors of Chembio or of any Affiliate of Chembio.

(a) Inverness and Chembio acknowledge that the license in this Section 2.3 is subject to the limitation that the Charlton Lateral Flow Patents (as described on Schedule E) are not licensed for the Over-The-Counter market; such Charlton Lateral Flow Patents are licensed only with respect to products for sale through any channels for use by licensed professional health-care providers (including hospitals, physicians acting as such and licensed professional health-care centers).

2.4. **Patent Marking**

. Chembio will include the patent numbers of the Inverness Lateral Flow Patents and indicate Inverness' and its licensors ownership of such patents on the packaging for all HIV Cassette Products, as set forth in Section 8.4.

2.5. **SDS Access**

. It is understood by the Parties that SDS shall not be entitled to receive copies of this agreement and any amendments as if and when effected.

2.6. **Termination of Licenses Upon Challenge of Validity**

. In all jurisdictions where such agreement is permitted by law, and to the maximum extent so permitted: (a) Chembio agrees not to Challenge any Patent Rights of Inverness or its Affiliates in the Inverness Lateral Flow Patents listed on Schedule E; and (b) Inverness agrees not to Challenge any Patent Rights in the Chembio Listed Patents. In addition to the foregoing, and whether or not the foregoing prohibition is permissible or otherwise enforceable, in the event that Inverness Challenges any Patent Rights in the Chembio Listed Patents, or Chembio Challenges any Patent Rights in the Inverness Lateral Flow Patents, the Party whose right is Challenged shall have the right, in its sole discretion and immediately on written notice to terminate this Agreement for cause. In the event that such termination arises: (a) due to Challenge by Inverness, Section 13.4 shall apply; (b) due to Challenge by Chembio, Section 13.5 shall apply. Each Party shall cause its Affiliates to refrain from any Challenge that the Party agrees not to make and the consequences of a Challenge by a Party's Affiliate shall be the same as a Challenge by the Party itself.

3. **Termination of Exclusivity in Event of Competition.**

(a) Chembio acknowledges that Inverness may Exploit any product that competes with the HIV Cassette Product, other than a Visual-Read HIV Test in the Barrel Field (a "**Permitted Competing Product**"**)**. Without limitation of the foregoing, any Visual-Read HIV Test that does not fall within the Barrel Field, whether or not Exploitation of such Visual-Read HIV Test by a Third Party would infringe the Inverness Lateral Flow Patents, is a Permitted Competing Product. Inverness shall give Chembio written notice of its intention to Exploit a Permitted Competing Product. Such notice shall be given by Inverness by the later of: (i) 60 days before such Permitted Competing Product is first shipped by Inverness to a US customer or Distributor, and (ii) the time that Inverness is first able to give such notice without violation of applicable law, regulation, agreement, or the rules of any securities exchange on which its securities are listed. Chembio specifically acknowledge that nothing in this Agreement shall be construed as limiting Inverness' right to acquire, develop, import, sell and/or manufacture Permitted Competing Products.

(b) At any time after receipt of notice from Inverness pursuant to Section 3(a), or after First Commercial Sale of a Permitted Competing Product , Chembio may either:

(i) by written Non-Exclusivity Notice to Inverness (a "**Non-Exclusivity Notice**"), convert Inverness's exclusive right to distribute the HIV Cassette Product in the United States into a non-exclusive right, in which case the non-exclusive, royalty-bearing license set forth in Section 2.3 shall automatically be expanded to allow Chembio to manufacture the HIV Cassette Product for sale in the United States, and to appoint Third Party Distributors to Exploit the HIV Cassette Product in the United States, subject to payment of royalties as set forth in Section 5.5; or

(ii) by written notice to Inverness, terminate the Cassette Agreement, such termination to take effect 60 days after written notice of termination is given, in which case Section 13.4 shall apply.

(c) Notwithstanding anything in this Section 3 to the contrary, Inverness's continued sales outside the United States of products for which a First Commercial Sale has been made as of the Effective Date of this Agreement, and improvements to such products, that compete with the HIV Cassette Products (whether or not they constitute Visual-Read HIV Tests, are in a cassette format, and/or are within the scope of the claims of any of the Inverness Lateral Flow Patents) shall not trigger Inverness's loss of exclusivity hereunder.

(d) For the avoidance of doubt, Inverness will have the right to acquire, develop, import, sell and/or manufacture any competing product (whether or not a Permitted Competing Product) without loss of its exclusivity pursuant to Section 3(b) if Chembio breaches its obligation to supply Inverness' requirements for HIV Cassette Products hereunder, but only for so long as any breach remains uncured.

4. **Limits to Scope of Inverness Licenses**

(a) The parties acknowledge that: (a) the HIV Products may be divided into the "**Existing Products**", meaning the HIV Cassette Product as it exists on the Effective Date, and the "**Future Products**", meaning any modifications to, or future versions of, the HIV Cassette Product made after the Effective Date; and (b) the Inverness Lateral Flow Patents may be divided into "**Current Lateral Flow Patents**" and "**Future Lateral Flow Patents**". The "**Current Lateral Flow Patents**" are: (i) the patents and patent applications on Schedule F; (ii) any continuations and divisionals of the patents and patent applications on Schedule F; (iii) any continuations-in-part of the patents and patent applications on Schedule F to the extent the claims thereof are directed to subject matter specifically described in (i) and (ii) above; and (iv) any foreign counterparts of the patents and patent applications described in (i) (ii) and (iii) above. The "**Future Lateral Flow Patents**" means any continuation-in-part of the Current Lateral Flow Patents not described in (iii) above, and any foreign counterpart of such continuation-in-part. All licenses granted by Inverness in this Agreement grant licenses to the Current Lateral Flow Patents with respect to both Existing Products and Future Products. The licenses granted by Inverness in this Agreement grant licenses to Future Lateral Flow Patents: (a) for Existing Products; and (b) for Future Products, but only with respect to claims in the Future Lateral Flow Patents that are infringed by the making, using, selling or importing of any Existing Product. Otherwise, Inverness grants no right or license to any Future Lateral Flow Patents under this Agreement, including without limitation any license to any Future Lateral Flow Patent except as described in the foregoing sentence.

(b) The Parties acknowledge that any licenses to the Inverness Lateral Flow Patents are subject to the limitation that the Charlton Lateral Flow Patents (as described on Schedule F) are not licensed for the Over-The-Counter market; such Charlton Lateral Flow Patents are licensed only with respect to products for sale through any channels for use by licensed professional health-care providers (including hospitals, physicians acting as such and licensed professional health-care centers).

5. **Royalties and Payments.**

5.1. **Exclusive Payment Arrangements**

. This Article 5 describes the manner in which the Parties will share revenues derived from the sale of HIV Cassette Products. Except as set forth in Section 13.4, no other fees, payments or royalties are due from any Party to any other Party with respect to the licenses and rights set forth in this Agreement.

5.2. **Pricing of HIV Cassette Products**

. Subject to the limitations set forth in this Article 5, each Party that sells any HIV Cassette Products hereunder may set the prices at which it sells such HIV Cassette Products in its sole and absolute discretion.

5.3. **Inverness Sale of HIV Cassette Products - Division of Net Sales**

(a) The Parties shall share Net Sales of HIV Cassette Products in accordance with the formula set forth in Schedule K.

(b) In the event that the Chembio Profit Share (the amount identified by (iii) on Schedule K) is less than 15% of Costs no sale shall occur unless both parties consent.

(c) Shares of Net Sales will be separately calculated and reported on a quarterly basis, and not on an order-by-order basis.

5.4. **Payment Mechanism for HIV Cassette Products Sold by Inverness**

. Inverness shall pay Chembio its Costs of HIV Cassette Products in accordance with the following procedure:

(a) For the six months following the Effective Date, the parties agree that the estimated per-unit amount representing Chembio's Costs for HIV Cassette Products to be supplied by Chembio to Inverness ("**Deemed Cost**") shall be the amount set forth on Schedule L, and the estimated per-unit amount representing Inverness' Net Sales for HIV Cassette Products sold by Inverness ("**Deemed Price**") shall be the amount set forth on Schedule L. For the remainder of the Term, the Deemed Cost and Deemed Price shall be adjusted each quarter based on the actual per-unit Cost of HIV Cassette Products, and the actual per-unit Net Sales for HIV Cassette Products, in the latest quarter for which actual Costs and Net Sales have been reported pursuant to Section 5.7.

(b) Each shipment of HIV Cassette Products by Chembio shall be accompanied by an invoice, in a form reasonably satisfactory to Inverness, for the HIV Cassette Products in the shipment at the then-current Deemed Cost (as hereinafter defined). Within thirty (30) days of receipt of a duly issued invoice for HIV Cassette Product shipped by Chembio in accordance with this Agreement, Inverness shall pay Chembio, for such HIV Cassette Products, the Deemed Cost of such HIV Cassette Products, and any additional amount due to Chembio pursuant to Schedule K, based on the then-current Deemed Cost and Deemed Price.

(c) Any adjustments to actual Costs for overpayments or underpayments made by Inverness shall be made pursuant to the quarterly accountings set forth in Section 5.7. For purposes of these calculations, Cost of HIV Cassette Product will be matched to sales on a FIFO basis.

5.5. **Royalties Payable by Chembio on Inverness Lateral Flow Patents**

. Chembio shall pay Inverness royalties of: (a) five percent (5%) of Net Sales of HIV Cassette Products sold by Chembio and its Affiliates in Developing Countries; and (b) eight and a half percent (8.5%) of Net Sales of HIV Cassette Products sold by Chembio and its Affiliates in the Rest of the World excluding Developing Countries. For the purposes of this paragraph, HIV Cassette Products are "sold" in a particular region, such as a Developing Country, when a sale is made to a Distributor that is located in such region; provided, however that Inverness reserves the right to charge the higher royalty rate if it can reasonably show that a Distributor located in a Developing Country is selling HIV Cassette Products to a purchaser located in a non-Developing Country, and Inverness shall charge the lower royalty rate if Chembio can reasonably demonstrate that its Distributor or purchaser located in a non-Developing Country has purchased goods for sale or distribution in a Developing Country.

(a) No royalties shall be payable unless the HIV Cassette Product infringes a Valid Claim of the Inverness Lateral Flow Patents in the country in which the HIV Cassette Product is manufactured or the country in which the HIV Cassette Product is sold.

(b) Only one royalty shall be due Inverness for any HIV Cassette Product regardless of the number of Valid Claims of the Inverness Later al Flow Patents that would be infringed.

(c) The obligation to pay royalties on Net Sales of HIV Cassette Product shall be imposed only once with respect to each HIV Cassette Product, even if such HIV Cassette Product is sold more than once in the course of its transfer to the ultimate end-user.

(d) The above royalties on HIV Cassette Products are not payable by Chembio with respect to HIV Cassette Products distributed by Inverness, for which the revenue sharing arrangements set forth in Section 5.3 are the sole and exclusive payment arrangements between the parties.

5.6. **Payment by Inverness for Samples**

. Inverness shall pay Chembio 110% of the Costs associated with the manufacture by Chembio of HIV Cassette Products that are used by Inverness for demonstrations, testing, clinical trials, sample and compassionate or similar use.

5.7. **Reporting and Calculation of Payments**.

(a) For any calendar quarter for which payments under Section 5.3 are due to Chembio, Inverness shall deliver to Chembio, within sixty (60) days after the end of such calendar quarter, reasonably detailed written accountings of Net Sales of the HIV Cassette Products during such calendar quarter. Such report shall indicate Net Sales on a country-by-country and HIV Cassette Product-by-HIV Cassette Product basis (and not on an order-by-order basis).

(b) Within seventy-five (75) days of the end of each calendar quarter during the Term, Chembio shall deliver to Inverness a complete and accurate accounting of all Costs and a determination of the cost per unit for all HIV Cassette Products sold to Inverness pursuant to this Agreement. The Costs reflected shall be the basis for payments to Chembio to be made by Inverness pursuant to Schedule K. The per-unit allocation of Costs to products sold shall be determined on a FIFO basis. Cost so determined shall remain in effect until the next such accounting.

(c) Within ninety (90) days after the end of any calendar quarter for which reports have been delivered pursuant to sub-paragraphs (a) and (b) above, Inverness shall deliver Chembio a report showing the calculation of the amounts due to Chembio pursuant to Schedule K, and any payments to be made hereunder. Such payments may be payable from either Inverness or Chembio, depending on whether Chembio has been underpaid or overpaid pursuant to the procedure set forth in Section 5.4, and shall be made no later than seven days after delivery of such report. With respect to Net Sales invoiced in a currency other than United States Dollars, Net Sales and royalties payable shall be expressed in their United States dollar equivalent, calculated using an average exchange rate for buying United States dollars published by The Wall Street Journal during the calendar quarter. All payments due to Chembio hereunder shall be made from the United States in United States dollars by transfer to such bank account as Chembio may designate.

(d) For any calendar quarter for which payments are due under Section 5.5 or Section 13.4(c) to Inverness, Chembio shall deliver Inverness, within sixty (60) days after the end of such calendar quarter, reasonably detailed written accountings of Net Sales of the HIV Cassette Products during such calendar quarter. Such report shall indicate Net Sales on a country-by-country and HIV Cassette Product-by-HIV Cassette Product basis, and the calculation of the royalty due to Inverness, and any payments to be made hereunder. When Chembio delivers such accountings, it shall also deliver all payments due under this Agreement to Inverness for such calendar quarter. With respect to Net Sales invoiced in a currency other than United States Dollars, Net Sales and royalties payable shall be expressed in their United States dollar equivalent, calculated using an average exchange rate for buying United States dollars published by The Wall Street Journal during the calendar quarter. All payments due from Chembio hereunder shall be made from the United States in United States dollars by transfer to such bank account as Inverness may designate.

(e) Chembio shall keep complete and accurate records of the latest two (2) years of Costs of HIV Cassette Products sold to Inverness hereunder. For the sole purpose of verifying Costs to be reimbursed to Chembio, Inverness shall have the right once per calendar year to retain an independent certified public accountant, selected by Inverness and reasonably acceptable to Chembio, to conduct an Audit in the location(s) where such records are maintained upon twenty (20) days prior written notice and during regular business hours, with all information disclosed being deemed Confidential Information hereunder. The cost of the Audit shall be paid by Inverness. Such Audit shall be completed within fifteen (15) business days, subject to extension by the auditor if the auditor reasonably determines in good faith that data or information it requires is not available and identifies the data or information required. Results of such review shall be made available to Chembio and Inverness. Inverness shall recalculate the payments made to the Parties and any Party overpaid shall promptly reimburse any underpaid Party. If a recalculation of Costs is equal to or greater than five (5%) percent of the correctly-calculated Costs, Inverness shall be entitled to have Chembio pay the reasonable out-of-pocket costs incurred by Inverness to retain such independent certified public accountant to conduct such review.

(f) Each Party due to make payments based on Net Sales hereunder ("Payer") shall keep complete and accurate records of the latest two (2) years of sales of HIV Cassette Products to which royalties or shares of Net Sales attach hereunder. For the sole purpose of verifying payments due to the payee Party ("Payee"), said Payee shall have the right, once per calendar year, to retain an independent certified public accountant, selected by said Payee and reasonably acceptable to the Payer, to conduct an Audit in the location(s) where such records are maintained upon twenty (20) days prior written notice and during regular business hours, with all information disclosed being deemed Confidential Information of the Payer. Such Audit shall be completed within fifteen (15) business days, subject to extension by the auditor if the auditor reasonably determines in good faith that data or information it requires is not available and identifies the data or information required. Whichever Party requests the Audit shall bear the costs thereof. Results of such review shall be made available to the Payer and the relevant Payee. If the Audit reflects an underpayment of amounts due, such underpayment shall be promptly remitted to the appropriate Payee by the Payer. If the underpayment is equal to or greater than five (5%) percent of the amount that was otherwise due, the Payee shall be entitled to have the Payer pay the reasonable out-of-pocket costs incurred by the Payee to retain such independent certified public accountant to conduct such review.

(g) Whenever reports upon which payments are based are to be made by any Party, they shall be certified as correct by the Chief Financial Officer of the Party. In addition, to the extent required of a Party by the provisions of the Sarbanes-Oxley Act, each of the Parties shall make available information as may be required for proper certification in accordance with Section 404 and any rules promulgated thereunder.

6. **Regulatory and License Matters**.

6.1. **Facility Registration/Inspections**

. Chembio shall, if it has not done so prior to the Effective Date, register, at its expense, with FDA, in accordance with the Act, each establishment in which it intends to manufacture any HIV Cassette Product and maintain, at its expense, all such establishment registrations during the term of this Agreement. Chembio shall permit FDA and Inverness to inspect each such establishment for purposes of verifying Chembio's compliance with the Act, including GMPs and QSRs, and for purposes of verifying that all items being manufactured by Chembio for sale to Inverness hereunder are being manufactured in accordance with the applicable Specifications; Inverness' participation in such inspections shall be at Inverness' cost. Any such inspection by Inverness shall be conducted upon reasonable advance notice to Chembio during the normal business hours of the facility to be inspected. Chembio acknowledges and agrees that no inspection by Inverness pursuant to this Section 6.1 shall relieve or diminish any of Chembio's obligations hereunder.

6.2. **Regulatory Filings**

. Subject to sub-paragraph (a) immediately below, Chembio shall be responsible for (1) obtaining and maintaining, and (2) paying for the obtaining and maintaining of, regulatory approvals required for the lawful distribution and sale of HIV Cassette Products in the applicable territories, including the costs of the CLIA waiver for the HIV Cassette Product in the United States, provided however that Inverness acknowledges that Chembio is under no obligation to obtain approval for Over-The-Counter sales of the HIV Cassette Product in the United States.

(a) In the event that the FDA issues a regulation providing for the lawful sale of the HIV Cassette Product for Over-The-Counter uses in the United States, Chembio may issue Inverness a written notice requiring Inverness to decide whether or not Inverness wishes to pursue obtaining FDA approval to sell the HIV Cassette Product for Over-The-Counter uses in the United States, with costs for obtaining such approval to be shared equally between Inverness and Chembio. Inverness shall have until the last to occur of (i) 12 months after the FDA formally promulgates the relevant regulation, and (ii) three (3) months after such notice is given by Chembio ("Notice Response Period"), to respond to such notice by informing Chembio whether it wishes to pursue such approval. If Inverness fails within the Notice Response Period to notify Chembio that it wishes to pursue Over-The-Counter approval for the HIV Cassette Product, Chembio may pursue such approval itself, at its own cost, and may Exploit the HIV Cassette Product in the Over-The-Counter market itself or through any Third Party Distributor; in such event, the Over-The-Counter market shall be excluded from the exclusive license granted by Chembio in Section 2.2, and the license granted by Inverness in Section 2.3 shall be expanded to include the Over-The-Counter market in the United States, subject always to payment by Chembio of royalties as set forth in Section 5.5.

6.3. **Bio-Rad Laboratories, Inc**

. Inverness shall use reasonable commercial efforts to obtain and maintain licenses for any and all intellectual property necessary from Bio-Rad Laboratories Inc. to permit Inverness to Exploit the HIV Cassette Products in the United States, provided any license fees or royalties payable may be deducted from gross sales pursuant to sub-paragraph (vi) of the definition of "Net Sales" as set forth herein. Inverness is aware of the royalties requested by Bio-Rad Laboratories, Inc. and agrees that it will pay appropriate royalties if a license can be obtained.

7. **Manufacture and Sale**.

7.1 **Chembio Efforts**

. Chembio shall use commercially reasonable efforts to manufacture the HIV Cassette Product and to supply all of Inverness' requirements for such product, in accordance with the published specifications for each such HIV Cassette Product (the "**Specifications**") and the supply requirements and limitations set forth in this Section 7.

7.2 **Forecasts**

. During the Term, Inverness shall provide Chembio, on a quarterly basis, with forecasts of Inverness's anticipated orders for the HIV Cassette Product during the succeeding three (3) quarters. The initial forecast shall be produced and delivered by Inverness to Chembio by the later of 60 days after the Effective Date or 60 days after the CLIA waiver is obtained. Chembio hereby

acknowledges and agrees that Inverness shall have the right to revise any quarterly forecast issued pursuant to this Section at any time upon notice given to Chembio not less than three months before the forecast delivery date for any products; any forecasts for delivery less than three months from the forecast date shall be binding on both parties. Inverness shall issue purchase orders and accept delivery of not less than ninety (90%) percent of the forecast quantity. Chembio shall not be required to timely deliver more than one hundred and twenty-five (125%) percent of the forecast quantity, but shall deliver not less than 100% of the quantity required by Inverness' binding forecasts.

7.3 **Purchase Orders**

. All sales and purchases of the HIV Cassette Product, if any, hereunder shall be initiated pursuant to Inverness's purchase order for the same placed with Chembio. Such purchase orders shall include relevant details of the order such as quantity, the current Costs of each HIV Cassette Product, destination, billing and shipping information, and requested delivery date(s) (a "**Purchase Order**"). Chembio shall accept Purchase Orders by written notice to Inverness within five (5) days of receipt. In the event that Chembio cannot comply with a delivery date requested by Inverness in any Purchase Order, Chembio may request an alternative delivery date, which shall be not more than forty-five (45) days after the date requested by Inverness. Any terms and conditions contained in any Purchase Order or written acceptance of a Purchase Order, invoice or other writing delivered by Chembio to Inverness or by Inverness to Chembio that are inconsistent with the terms and conditions of this Agreement shall be null and void and of no effect unless agreed to in a writing executed by an authorized representative of Inverness and Chembio. At any time up to ten (10) days prior to the delivery date set forth in any Purchase Order, Inverness may issue an alteration to a Purchase Order in order to (i) change a location for delivery, (ii) correct typographical or clerical errors, or (iii) reschedule a delivery. In such event, Inverness shall reimburse Chembio for all reasonable resulting costs incurred by Chembio and notified by Chembio to Inverness within seven (7) days after alteration of the purchase order.

7.4 **Shipment Terms**

. HIV Cassette Product ordered by Inverness shall be shipped FOB, point of manufacture, with the carrier and to the destination specified in the Purchase Order.

7.5 **Acceptance**

. Within twenty (20) days after receipt of any HIV Cassette Products, Inverness shall inspect and, in its discretion, test the HIV Cassette Products to determine whether they conform in all material respects to the Specifications. In the event an HIV Cassette Product does not so conform, Inverness may within such twenty (20) day period (i) continue to test the HIV Cassette Product, or (ii) return the non-conforming HIV Cassette Product and Documentation to Chembio, at Chembio's expense, and any amounts paid by Inverness for the HIV Cassette Product returned shall be refunded by Chembio to Inverness. If Inverness does not return a non-conforming HIV Cassette Product within such twenty (20) day period, it is deemed accepted.

7.6 **Sales Effort**

. Inverness shall use commercially reasonable efforts to launch, promote, develop a demand for the HIV Cassette Product, and to Exploit the HIV Cassette Products to the markets for which regulatory approvals have been obtained in the United States and perform such responsibilities diligently, with the objective of maximizing the sales potential of those products and promoting the benefits thereof in the most commercially beneficial manner.

7.7 **Inverness Responsibilities; Rights**

. In connection with its responsibilities for distribution, marketing and sales of the HIV Cassette Products (as permitted in this Agreement), Inverness shall provide all sales force (including, without limitation, sales administration and training), order entry, customer service, reimbursement management, medical affairs, medical information, marketing (including all advertising and promotional expenditures), warehousing, physical distribution, invoicing, credit and collections, production forecasting and other related facilities and services as it deems necessary or desirable for such distribution, marketing and sales.

7.8 **Marketing Plans and Budgets**

. Inverness shall prepare proposed marketing and promotional plans for the HIV Cassette Products (as permitted in this Agreement), which shall include plans related to the prelaunch, launch, promotion and sales of the HIV Cassette Products and which shall include but not be limited to pricing strategy, sales targets, forecasts for the number of sales representatives, copies of promotional materials and a reasonably descriptive overview of the marketing and advertising campaigns proposed to be conducted (the "Marketing Plans"). Inverness shall review the proposed Marketing Plans with Chembio as soon as practicable after preparation and as frequently as may be required based upon Inverness' usual marketing campaign cycles, but in no case less that once each calendar year during the Term. Inverness shall consider comments from Chembio on the Marketing Plans in good faith, but Chembio shall have no right of approval with respect to such Marketing Plans. Inverness shall meet with Chembio at their request but no more than on a quarterly basis to discuss sales activity and results in each market segment.

8. **Trademarks**

8.1. **Trademark License**

. Chembio hereby grants Inverness, to the extent that Chembio possesses such rights, a worldwide, royalty-free license during the Term to use the Chembio Trademarks in connection with any advertisement and promotion of the HIV Cassette Products authorized hereunder. All such use of the Chembio Trademarks shall inure to the benefit of Chembio. Inverness hereby grants Chembio a non-exclusive, non-transferable license to use the Inverness Trademarks, but only for the purpose of labeling and packaging the HIV Cassette Products for sale to Inverness. All such use of the Inverness Trademarks shall inure to the benefit of Inverness. Neither party shall use or alter such marks in a manner which may jeopardize or diminish the other party's rights to use them, and all notices of rights therein and all notices of any patent and/or patent pending rights to the HIV Cassette Products shall be clearly designated in all written materials in which such marks are used.

8.2. **Compliance with Law; Registration**

. Each Party, in using the other Party's trademarks, shall use such marks and/or names only in such manner as will comply with the provisions of applicable trademark laws. Any and all trademark applications which are filed in any jurisdiction for a Party's trademarks shall be filed by that Party and that Party shall bear all costs incurred in connection with such trademark applications and registrations. No trademark costs incurred by Chembio shall be included in Costs.

8.3. **Termination**

. The licenses granted under Section 8.1 shall terminate upon any termination of this Agreement, and thereafter neither party shall use the other party's trade names, service marks, or trademarks except in connection with sale by Inverness of HIV Cassette Products purchased prior to the termination of this Agreement.

8.4. **Labeling**

. Inverness shall develop, produce and provide all labeling for the HIV Cassette Products, subject to Chembio's approval. All materials referring or relating to the HIV Cassette Products shall include the following in legible font: "Manufactured by Chembio Diagnostic Systems, Inc., Medford, NY for Inverness Medical Innovations under [patents no.s of Inverness Lateral Flow Patents] owned or licensed by Inverness Medical Innovations, Inc.".

9. **Prosecution and Enforcement of Licensed Intellectual Property**.

9.1. **Prosecution**

. The owner or Controller of Intellectual Property Rights (the "**Patent Owner**") (for example, Inverness in the case of the Inverness Lateral Flow Patents and Chembio in the case of the Chembio IP) shall have the sole right to prepare, file, prosecute, obtain and maintain throughout the world, and otherwise take all Patent Prosecution Actions with respect to its Intellectual Property Rights as such Patent Owner shall deem to be appropriate in its discretion. Each Patent Owner shall pay all Patent Costs incurred by it in connection with the foregoing activities and such Patent Costs shall not be deemed Costs hereunder. If it becomes necessary or desirable, the other Parties shall fully cooperate with the Patent Owner, at the Patent Owner's request and expense, in connection with all Patent Prosecution Actions; provided that no Party shall be obligated to provide such cooperation if, in its reasonable business judgment, such cooperation would be adverse to its interests outside this Agreement.

9.2. **Enforcement of Licensed Patents**

. The Patent Owner shall have the sole right to enforce and defend any of its Intellectual Property Rights licensed hereunder, at its own expense. Notwithstanding the foregoing, each of the Parties shall inform the other Parties promptly in writing of any alleged infringement, misuse or misappropriation by any Person of any Intellectual Property Rights licensed hereunder that affects the Exploitation of HIV Cassette Products or other products licensed hereunder, and the Parties shall reasonably consult with each other with respect to the strategy to resolve the alleged infringement, misuse or misappropriation. In the event that a Patent Owner shall initiate an infringement action or defend an action in accordance with this Section, the other Parties shall fully cooperate and supply such assistance as reasonably requested by the Patent Owner; provided that no Party shall be obligated to provide such cooperation if, in its reasonable business judgment, such cooperation would be adverse to its interests outside this Agreement.

10. **Confidentiality**.

10.1. **Limited Disclosure and Use**

. Each of Inverness and Chembio shall hold in confidence any Confidential Information disclosed by any other Party or otherwise obtained by such Party from any other as a result of this Agreement, and each of Inverness and Chembio shall protect the confidentiality thereof with the same degree of care that it exercises with respect to its own information of a like nature, but in no event less than reasonable care. Without the prior written consent of the disclosing Party, a receiving Party shall not use, disclose, or distribute any Confidential Information, in whole or in part, except as required to perform such Party's obligations or exercise such Party's rights hereunder. Access to the disclosing Party's Confidential Information shall be restricted to the receiving Party's employees and agents, who, in each case, need to have access to carry out a permitted use and are bound in writing to maintain the confidentiality of such Confidential Information.

10.2. **Exceptions**

. The obligations set forth in Section 10.1 shall not apply to any portion of the Confidential Information that the receiving Party can demonstrate by legally sufficient evidence: (i) now or hereafter, through no act or failure to act on the part of the receiving Party, is or becomes generally available; (ii) is known to the receiving Party at the time of receiving such Confidential Information and not subject to an obligation of confidentiality to a Third Party; (iii) is hereafter furnished to the receiving Party by a Third Party as a matter of right (and without violating any agreement with the disclosing Party) without restriction on use or disclosure; or (iv) is independently developed by the receiving Party without use of any Confidential Information received from the other Party. In addition, each receiving Party may disclose Confidential Information to the extent such disclosure is reasonably necessary to protect Intellectual Property Rights to which such Party has a license hereunder, to prosecute or defend litigation, to comply with applicable law or regulation, to obtain necessary or desirable regulatory approvals, to respond to a valid order of a court or other governmental body or any political subdivision thereof, or to conduct preclinical or clinical trials, provided that, other than with respect to disclosure for protecting Intellectual Property Rights, the receiving Party shall use reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed.

10.3. **Use of Name; Disclosure of Terms of the Agreement**

. Except as authorized in Section 8 hereof or otherwise required by applicable law, regulation or the rules of any securities exchange on which such Party's securities are listed, no Party shall use the names of the other Parties in any publicity or advertising without the prior written approval of the other Parties, except that any Party may disclose that they have entered into this Agreement. Except as may be required by applicable law, regulation or the rules of any securities exchange on which such Party's securities are listed, no Party shall disclose any terms or conditions of this Agreement without the prior written consent of the other Parties, provided that a Party may disclose such terms and conditions to any Third Party with whom such Party has entered into or proposes to enter into a business relationship (including any transaction that would result in a permitted assignment in accordance with the terms and conditions of Section 15.11), provided any such Third Party is informed of the confidentiality restrictions herein with respect to such terms and conditions and agrees to abide by such restrictions.

10.4. **Effect of Termination**

. Each Party shall, upon termination of this Agreement, immediately discontinue use of the other's Confidential Information. Within a reasonable time after termination of this Agreement, but in no event later than thirty (30) days thereafter, all materials containing such Confidential Information shall be returned by the receiving Party or (with the disclosing Party's prior written consent) destroyed, provided, however, that each Party may retain copies of Confidential Information in which the Party has a licensed interest that survives termination (e.g., as provided in Section 13.4 through 13.6).

10.5. **Survival**

. The confidentiality obligations set forth in this Section 10 shall survive any termination or expiration of this Agreement in perpetuity .

11. **Representations; Warranties**.

11.1. **Corporate Power**

. Each Party represents to the other Parties that it has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof. Each Party represents to the other that this Agreement constitutes a valid and binding agreement, enforceable against it in accordance with its terms.

11.2. **No Default or Violation**

. Each Party represents and warrants to the other Parties that the execution, delivery and performance of this Agreement does not (i) violate or require any registration, qualification, consent, approval, or filing under, (1) any law, statute, ordinance, rule or regulation, or (2) any judgment, injunction, order, writ or decree of any court, arbitrator, or governmental entity by which such Party or any of its assets or properties may be bound or (ii) conflict with, require any consent, approval, or filing under, result in the breach or termination of any provision of, constitute a default under, result in the acceleration of the performance of any obligations under, result in the vesting or enhancement of any other Person's rights under, or result in the creation of any lien upon any of such Party's properties, assets, or businesses pursuant to (x) its organizing documents or By-Laws or (y) any material indenture, mortgage, deed of trust, license, permit, approval, consent, franchise, lease, contract, or other instrument or agreement to which such Party is a Party or by which such Party or any of such Party's properties or assets is bound.

11.3. **Licensed Intellectual Property**

. Each Party licensing any Intellectual Property Rights (a "**Licensor**") to any other Party hereunder (a "**Licensee**") represents and warrants to each such Licensee that: (a) it has the full right, title and authority to grant to Licensee the licenses granted hereunder; and (b) to the best of the Licensor's knowledge and except as otherwise disclosed to the Licensee, all such licensed Patent Rights existing as of the Effective Date are valid and enforceable, and all patents, if any, issuing on any of the pending patent applications of the Patent Rights existing of the Effective Date will be valid and enforceable.

11.4. **Regulatory Matters**

. Chembio represents and warrants to Inverness that, at the time when HIV Cassette Products are delivered, it will have obtained regulatory approval under the Act which is required to permit Chembio to manufacture the HIV Cassette Products and sell the HIV Cassette Products to qualified customers in the United States professional market for use by such customers in accordance with and subject to the limitations contained within the information contained within Schedule D hereof and information related to the HIV Cassette Products that is listed by the FDA. Chembio represents and warrants that, with respect to the manufacture of the HIV Cassette Products, Chembio will comply with the requirements of the Act, and to the best of its knowledge, all other applicable federal and state laws.

11.5. **Product Quality**

. Chembio represents and warrants that:

(a) Each unit of HIV Cassette Product sold to Inverness hereunder shall be manufactured in accordance with and shall comply, at the time of delivery to Inverness, in all material respects with the applicable Specifications therefor, shall perform as intended in all material respects, and shall otherwise be free from defects in material and workmanship; and each unit of HIV Cassette Product sold to Inverness hereunder will not, at the time of delivery, be adulterated or misbranded within the meaning of the Act or within the meaning of any jurisdiction in which the definitions of misbranding and adulteration are substantially the same as in the Act, nor will any such unit of HIV Cassette Product, at the time of delivery to Inverness, be an article which may not, under the Act, be introduced into interstate commerce.

(b) In the event any unit(s) of HIV Cassette Product does not conform with a warranty set forth in Section 11.5(a) applicable thereto, Inverness or an Affiliate of Inverness may return such unit(s) of HIV Cassette Product within twenty (20 days of its receipt to Chembio and, in the event Inverness or an Affiliate of Inverness does so, Chembio, within thirty (30) days of its receipt of the return, shall either; (a) refund or credit Inverness's account in an amount equal to the purchase price paid by Inverness for such unit(s) of non-conforming HIV Cassette Product, as the case may be, plus freight and insurance charges incurred by Inverness and/or its Affiliate incident to the original and return shipment, as documented by Inverness, or (b) replace, without charge, the non-conforming unit(s) of HIV Cassette Product, as the case may be, with an equivalent number of like unit(s) HIV Cassette Product, as the case may be, conforming with the applicable warranties set forth in Section 11.5(a) and refund or credit Inverness's account in an amount equal to said original and return freight and insurance charges incurred as documented by Inverness. The cost of returned units and freight and insurance charges hereunder shall not be included in Costs.

11.6. **Exclusion of Other Representations and Warranties**

. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NO PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY REPRESENTATIONS OR WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT. NO PARTY WARRANTS THAT THE OTHER PARTIES WILL RECEIVE ANY PARTICULAR AMOUNT, OR ANY, REVENUES OR PROFITS AS A RESULT OF ENTERING INTO THE BUSINESS ARRANGEMENTS DESCRIBED IN THIS AGREEMENT.

12. **Indemnification**

12.1. **By Manufacturer**

. Each Party that manufactures, either directly or through a contract manufacturer, any HIV Cassette Product hereunder (a "**Manufacturer**") hereby agrees to indemnify, defend (using counsel selected by the Manufacturer which is reasonably acceptable to the other Party) and hold harmless the other Party, its Affiliates and their respective Distributors and customers, from and against any and all liabilities, losses, (exclusive of lost profits) damages, costs and expenses (including, without limitation, reasonable attorneys' fees, court costs, and out-of pocket expenses) suffered or incurred which arise or result from: (i) the material breach of any warranty or representation of the Manufacturer contained in this Agreement; (ii) any third party claim of personal injury (including death) or property damage arising in connection with any HIV Cassette Product manufactured by or for the Manufacturer; (iii) any material failure by the Manufacturer to perform any of the covenants, agreements or obligations of the Manufacturer contained in this Agreement; or (iv) any third party claim alleging that the manufacture, use, sale, offer for sale, import or export of the HIV Cassette Products manufactured by or for the Manufacturer infringes the proprietary rights of the third party claimant.

12.2. **By Sellers**

. Each seller of any HIV Cassette Product hereunder (a "**Seller**") hereby agrees to indemnify, defend (using counsel selected by the Seller which is reasonably acceptable to the other Party) and hold harmless the other Party from and against any and all liabilities, losses (exclusive of lost profits), damages, costs, and expenses (including, without limitation, reasonable attorneys' fees, court costs, and out-of pocket expenses) suffered or incurred by the other Party which arise or result from: (i) the material breach of any warranty or any representation of the Seller contained in this Agreement; (ii) any material failure by the Seller to perform any of its covenants, agreements, or obligations contained in this Agreement; or (iii) the promotion and sale by the Seller or any Affiliate or Distributor of the Seller of any HIV Cassette Product, except to the extent covered by the Manufacturer's defense and indemnification obligations under Section 12.1.

12.3. **Notice of Claims**

. Within thirty (30) days after a Person seeking indemnification hereunder (hereinafter the "**Indemnified Party**") has received notice of or has acquired knowledge of any claim by any Person not a Party to this Agreement of the commencement or threatened commencement of any action or proceeding by any Person not a Party to this Agreement ("**third party claim**") or has acquired knowledge of any other claim hereunder against another Party hereto ("**first party claim**") the Indemnified Party shall, if such claim is indemnifiable by the other Party pursuant hereto (hereinafter the "**Indemnifying Party**"), give the Indemnifying Party written notice of such claim and the commencement or threatened commencement of such action or proceeding, if any. Such notice shall state the nature and basis of such claim, and, if ascertainable, the amount thereof. Notwithstanding the foregoing, the failure of the Indemnified Party to give such notice shall not excuse the Indemnifying Party's obligation to indemnify and, in the case of a third party claim, defend the Indemnified Party, except to the extent the Indemnifying Party has suffered damage or prejudice by reason of the Indemnified Party's failure to give or delay in giving such notice. Within ten (10) business days of receipt of any notice issued by the Indemnified Party pursuant to this Section 12.3, the Indemnifying Party shall notify the Indemnified Party whether the Indemnifying Party acknowledges its indemnification obligation and, in the case of a third party claim, its defense obligation with respect to the claim which was the subject of the Indemnified Party's notice or whether it disclaims such obligations. In the event the Indemnifying Party disclaims or fails to timely acknowledge its obligations with respect to any claim by the Indemnified Party relating to any third party claim, the Indemnified Party shall have the right to defend such claim, with counsel of its own selection, and compromise such claim without prejudice to its right to indemnification hereunder. In the event the Indemnifying Party timely acknowledges its obligations hereunder with respect to any third party claim, the Indemnifying Party shall defend the same with counsel in accordance with this Section. Where the Indemnifying Party shall have acknowledged in writing its obligations hereunder with respect to any third party claim, the Indemnified Party may, at its expense, participate in the defense of such third party claim and no such third party claim shall be settled by the Indemnified Party without the prior written consent of the Indemnifying Party which consent shall not be unreasonably withheld or delayed. At any time after the Indemnifying Party acknowledges its obligations hereunder with respect to any third party claim, the Indemnifying Party may request the Indemnified Party to agree in writing to the payment or compromise of such third party claim (provided such payment or compromise has been previously approved in writing by the third party claimant), and, in the event the Indemnifying Party does so, the Indemnified Party shall promptly agree in writing to such settlement, unless such settlement would involve a remedy or remedies, other than the payment of money damages by the Indemnifying Party, to which the Indemnified Party reasonably objects.

12.4. **Disputes**

. In the event any party to this Agreement makes a claim against another Party under this Section 12 or in any way relating to or arising under this Agreement and further in the event the Party receiving notice of such claim fails to timely acknowledge its obligations hereunder with respect to such claim or disclaims such obligations, the relevant Parties, within forty (40) days of the date of issuance of notice by the Party making such claim, shall meet and attempt to resolve in good faith the dispute between or among the Parties with respect to such claim. If the Parties fail to resolve such dispute within seventy-five (75) days of the date of issuance of notice by the Party making such claim, the Party making such claim may thereafter commence to arbitrate the claim in accordance with the provisions set forth in Section 15.8. Upon resolution of any claim referred to in this Section 12, whether by agreement between the Parties to this Agreement or the rendering of a final arbitration award, the appropriate Party under such agreement or the Party against which the arbitration award is rendered shall, within ten (10) days of such resolution, pay over and deliver to the other Party funds in the amount of any claim as resolved.

13. **Term and Termination**.

13.1. **Term of Agreement**

. Unless otherwise terminated as expressly provided herein or with respect to any perpetual licenses granted herein, with respect to each HIV Cassette Product, the licenses granted and appointments made hereunder shall commence on the Effective Date and continue until May 31, 2016 (the "**Term**").

13.2. **Material Breach**

. If a Party:

(a) materially breaches this Agreement in a manner which cannot be cured;

(b) materially breaches this Agreement in a manner that can be cured and a Party has failed to take steps to begin to cure within ninety (90) days following written notice of breach by the Party or Parties affected by the breach or is not diligently pursuing a cure thereafter; or

(c) is subject to a petition for relief under any bankruptcy legislation, or makes an assignment for the benefit of creditors, or is subject to the appointment of a receiver for all or a substantial part of the Party's assets, and such petition, assignment or appointment, if involuntary, is not dismissed or vacated within ninety (90) days (each an "**Insolvency Event**"),

then, on each such occasion, the non-breaching Party shall have the right to exercise one or more of the following remedies: (x) upon written notice by the non-breaching Party to the breaching Party within thirty (30) days of the end of the applicable cure period (if any) (assuming that the non-breaching Party has not already given such a notice upon the occurrence of a prior material, uncured breach by the breaching Party), the non-breaching Party shall have the right to seek monetary damages for such material breach within the limitations set forth in Section 14 hereof and/or equitable relief to prevent such material breach from continuing or occurring again in the future; and, at its option, the non-breaching Party shall have the right to terminate the rights of the breaching Party licensed hereunder upon written notice to breaching Party. Notwithstanding the foregoing, the obligations of the breaching Party, including the licenses granted and appointments made hereunder to the non-breaching Parties shall continue unless the non-breaching Party agrees that such licenses and appointments shall terminate. Notwithstanding the foregoing, if Chembio shall be enjoined from supplying HIV Cassette Products to Inverness because of a lawsuit regarding Intellectual Property Rights of a Third Party, or Inverness shall be enjoined from selling HIV Cassette Products because of a lawsuit regarding Intellectual Property Rights of a Third Party, and such injunction shall in either case cause a material breach of this Agreement, the non-breaching Party shall not have the right to seek monetary damages for such material breach. Whenever a breach occurs and such breach can be cured in a timely manner, the non-breaching Party shall cooperate with the Party in breach and take reasonable steps (at the cost of the breaching Party) to allow the breaching Party to cure the breach.

13.3. **Section 365(n); Agreement to Deliver Embodiments**

. All rights and licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11, U.S. Code (the "**Bankruptcy Code**"), licenses of rights to "intellectual property" as defined in the Bankruptcy Code. The Parties agree that the licensee of such rights shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code. Chembio agrees during the term of this Agreement to create and maintain current copies or, if not amenable to copying, detailed descriptions or other appropriate embodiments, of all intellectual property and Technology used in the manufacture of the HIV Cassette Products ("**Escrow Materials**"). Chembio hereby grants to Inverness, with effect from the Effective Date, a non-exclusive, royalty-free, perpetual license under the Chembio IP to use the Escrow Materials to Exploit the HIV Products, and, if Chembio fails to supply HIV Products to Inverness as required by this Agreement, to manufacture and have manufactured the HIV Products; provided however that Inverness shall not exercise such license unless Chembio suffers an Insolvency Event. In the event that Inverness obtains the right to manufacture the HIV Cassette Products in accordance with this Agreement, Inverness shall be entitled to copies of all Escrow Materials. All rights, powers and remedies of the Inverness provided under this Section 13.3 are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity in the event of any such commencement of a bankruptcy proceeding by or against the Chembio.

13.4. **Effect of Termination for Breach by Inverness**

. Upon any termination made in accordance with Section 3(b)(ii) by Chembio for sale of a Permitted Competing Product, or in accordance with Section 13.2(a) or 13.2(b) by Chembio for breach by Inverness:

(a) The license grants contained in Section 2.2, and the non-compete obligations in Section 3, shall terminate;

(b) Inverness may sell any inventory of HIV Cassette Products in its possession at the effective date of termination, but shall have no further right to Exploit the HIV Cassette Products; and

(c) on and subject to the limitations set forth in this Agreement, Chembio shall have a perpetual, irrevocable, non-transferable, non-exclusive, license, without right to sub-license, under the Inverness Lateral Flow Patents to Exploit the HIV Cassette Product in the United States itself or through Third parties, at a royalty of 8.5% of Net Sales in the United States, subject to the royalty payment limitations set forth in 5.5(a), 5.5(b) and 5.5(c).

13.5. **Effect of Termination for Breach by Chembio**

. Upon any termination made in accordance with Section 13.2(a) or 13.2(b) by Inverness for breach by Chembio:

(a) The license grant contained in Sections 2.2 shall automatically be expanded to permit Inverness to manufacture or have manufactured the HIV Cassette Product, and such licenses shall continue after termination and shall be perpetual and irrevocable, subject to payment of royalties of five percent (5%) of Net Sales in Developing Countries, and eight and a half percent (8.5%) of Net Sales in the Rest of the World excluding Developing Countries; and

(b) Chembio shall, at the written request of Inverness and at no cost to Inverness, provide copies of all technical information, including all Technology in the Chembio IP, reasonably necessary for Inverness to manufacture, have manufactured and Exploit the HIV Cassette Products.

13.6. **Survival**

. No expiration or termination of this Agreement shall affect any rights or liabilities of the Parties which may have accrued prior to the date of expiration or termination. Notwithstanding anything herein to the contrary, upon any expiration or termination of this Agreement, in addition to any provisions that by their terms survive, the provisions of Sections 5.7, 9, 10, 11.5(b), 12, 13.3, 13.4, 13.5, 13.6, 14 and 15 shall survive and shall continue in full force and effect in accordance with their respective terms.

14. **Limitation of Liability**.

14.1. **Exclusion of Liability for Certain Damages**

. EXCEPT FOR BREACHES OF ITS CONFIDENTIALITY OBLIGATIONS HEREUNDER AND FOR VIOLATIONS OF ANOTHER PARTY'S INTELLECTUAL PROPERTY RIGHTS AND FOR DAMAGES CAUSED BY A PARTY'S GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT, IN NO EVENT SHALL A PARTY BE LIABLE TO THE OTHER PARTY FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING, WITHOUT LIMITATION, DAMAGES RESULTING FROM LOSS OF USE, PROFITS, BUSINESS OR GOODWILL, WHETHER OR NOT THE PARTY ALLEGEDLY CAUSING THE DAMAGE HAS BEEN ADVISED OF THE POSSIBILITY THEREOF. THIS SECTION 14 SHALL NOT BE CONSTRUED TO LIMIT ANY PARTY'S INDEMNIFICATION OBLIGATIONS UNDER SECTION 12 HEREOF.

14.2. **Limitation on Liability for Direct Damages**

. EXCEPT FOR BREACHES OF ITS CONFIDENTIALITY OBLIGATIONS HEREUNDER AND FOR VIOLATIONS OF ANOTHER PARTY'S INTELLECTUAL PROPERTY RIGHTS, FOR DAMAGES CAUSED BY A PARTY'S GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT, OR FOR ANY PARTY'S INDEMNIFICATION OBLIGATIONS UNDER SECTION 12 HEREOF, EACH PARTY'S MAXIMUM AGGREGATE LIABILITY TO THE OTHER PARTY SHALL IN NO EVENT EXCEED THE AMOUNT OF $1 MILLION, WHETHER SUCH DAMAGES ARISE IN CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY OR OTHERWISE.

15. **General**.

15.1. **Waivers and Amendments**.

(a) This Agreement may be amended, modified or supplemented only by a written instrument executed by the Parties hereto.

(b) No waiver of any provision of this Agreement, or consent to any departure from the terms hereof, shall be effective unless the same shall be in writing and signed by the Party waiving or consenting thereto. No failure on the part of any Party to exercise, and no delay in exercising, any right or remedy hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such right or remedy by such Party preclude any other or further exercise thereof or the exercise of any other right or remedy. The waiver by any Party hereto of a breach of any provision of this Agreement shall not operate as a waiver of any subsequent breach. All rights and remedies hereunder are cumulative and are in addition to and not exclusive of any other rights and remedies provided by law.

15.2. **Entire Agreement**

. This Agreement, the Schedules hereto and the Related Documents constitute the entire agreement among the Parties hereto with respect to the subject matter hereof and supersede all prior agreements and understandings, whether written or oral, among the Parties, or any of the Parties, in connection with such subject matter.

15.3. **Severability**

. If any provision of this Agreement is found invalid or unenforceable by a court of competent jurisdiction, such provision shall be enforced to the maximum extent permissible by law and the other provisions of this Agreement shall remain in full force and effect.

15.4. **Relationship of the Parties**

. This Agreement shall not constitute any Party the agent or legal representative of any other Party for any purpose whatsoever, and no Party shall hold itself out as an agent of any other Party. This Agreement creates no relationship of joint venturers, partners, associates, employment or principal and agent between or among the Parties, and each of the Parties is acting as an independent contractor. No Party is granted herein any right or authority to, and shall not attempt to, assume or create any obligation or responsibility for or on behalf of any other Party. No Party shall have any authority to bind any other Party to any contract, whether of employment or otherwise, and each Party shall bear all of their respective expenses for its operations, including, without limitation, the compensation of its employees and salespersons and the maintenance of its offices, service and warehouse facilities. Each Party shall each be solely responsible for its own employees and salespersons and for their acts and the things done by them.

15.5. **No Election of Remedies**

. The rights and remedies accorded herein are cumulative and in addition to those provided by law, and may be exercised separately, concurrently, or successively.

15.6. **Notices**

. All notices and other communications hereunder shall be in writing and shall be deemed given if delivered personally, telecopied (with confirmation) or mailed by registered or certified mail (return receipt requested) or delivered by recognized courier service providing evidence of delivery to the Parties at the following addresses:

(a) if to Chembio, to:

Chembio Diagnostic Systems, Inc.
3661 Horseblock Road
Medford, New York 11763

Attention: Lawrence A. Siebert, President
Telecopier No.: (631) 924-6033

with a copy to:

Ruskin Moscou Faltischek, P.C.
1425 Reckson Plaza
15th Floor, East Tower
Uniondale, New York 11556

Attention: Michael L. Faltischek, Esq.,
Telecopier No.: (516) 663-6640

(b) if to Inverness, to:

Inverness Medical Innovations, Inc.
51 Sawyer Road,
Waltham MA 02454
Attention: General Counsel's office
Telecopier: (781) 314 4073

or at such other address for a Party as shall be specified by like notice.

15.7. **Governing Law**

. This Agreement shall be governed by, and construed and enforced in accordance with, the substantive laws of the State of New York , without giving effect to its conflicts of laws rules.

15.8. **Dispute Resolution**

. In the event of any dispute or disagreement between or among any of the Parties as to the interpretation of any provision of this Agreement or the performance of any obligations hereunder, the matter, upon written request of any Party, shall be referred to mediation and arbitration in accordance with the procedures set forth in Schedule H to this Agreement.

15.9. **Waiver of Jury Trial**

. The Parties each hereby irrevocably and unconditionally waives all rights to trial by jury in any legal action, proceeding or counterclaim with respect to any matter whatsoever arising out of or in connection with or related to this Agreement or the enforcement thereof.

15.10. **Counterparts**

. This Agreement may be executed in two or more counterparts, all of which shall be considered one and the same agreement and shall become effective when two or more counterparts have been signed by each of the Parties and delivered to the other Parties, it being understood that all Parties need not sign the same counterpart. Facsimile execution and delivery of this Agreement by any of the Parties shall be legal, valid and binding execution and delivery of such document for all purposes.

15.11. **Assignment**

. This Agreement is personal to each of the Parties, and no Party shall assign any of its rights or delegate any of its obligations hereunder, including without limitation by operation of law, Change of Control or otherwise, without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed, provided, however, that without the consent of Chembio, Inverness may (i) assign its rights under this Agreement and delegate its obligations hereunder, in whole or in part, to any Person that shall acquire the business of Inverness to which this Agreement relates, or to any Affiliate of such Party, if the assignee shall assume Inverness' obligations hereunder in writing, and (ii) assign this Agreement in connection with a sale or transfer of substantially all of the assets of, or a majority interest in the voting shares of, Inverness or its corporate parent to, or the merger or consolidation of Inverness or its corporate parent with or into, any other Person. In this paragraph, "Change of Control" means any sale of the equity securities of a Party following which the equity holders of such Party immediately prior to such sale own, directly or indirectly, less than 50% of the combined voting power of the outstanding voting securities of such Party, other than in a transaction involving a sale of equity securities for the purpose of raising capital to a group of financial investors in which not less than 50% of such equity securities are purchased by a recognized venture capital or private equity fund or funds and where the management of the selling Party before the financing is substantially the same as the management of such Party after the financing.

15.12. **Force Majeure**

. No Party shall be liable for failure to perform any of its obligations under this Agreement when such failure is due to fire, flood, strikes, labor troubles or other industrial disturbances, legal restriction, riot, insurrection, or any other cause beyond the reasonable ability of the Party affected thereby to foresee and avoid, and without such party's fault or negligence ("Force Majeure"), provided that any Party claiming the existence of Force Majeure shall give notice to the other parties not more than seven (7) days after the commencement of the event of Force Majeure, and shall use prompt and diligent efforts to mitigate the effects of Force Majeure. In the event that any event of Force Majeure prevents performance for sixty (60) days or more, any other party may terminate this Agreement on written notice to all parties.

15.13. **Further Assurances**

. Each Party hereto will, upon the request of the other Party and without further consideration, execute and deliver such other instruments, and take such other actions, as such other Party may reasonably request, and at the other Party's expense, to more effectively and efficiently carry out the covenants, licenses and agreements of the Parties set forth in this Agreement and consummate the transactions contemplated by this Agreement. Without limitation of the foregoing, each exclusive licensee of rights granted hereunder shall have the right, at its sole cost and expense, to register, record and otherwise document such exclusive license in any country where there are any pending or issued Patent Rights. Such licensee may require that the other Party execute a "short form" license in order to effect the foregoing registration, recordal or other documentation in any such country, and may record such short form license, but no short form license shall in any way alter or otherwise affect the rights and obligations of the Parties hereunder.

[remainder of this page intentionally left blank]

* * *

IN WITNESS WHEREOF, the Parties have executed, or caused their duly authorized representatives to execute, this Agreement under seal as of the date first written above.

Chembio Diagnostic Systems, Inc.

By:
Title:

Inverness Medical Innovations, Inc.

By:
Title:

[Signature page to HIV Cassette License, Marketing and Distribution Agreement]

Execution Version

Non-Exclusive License, Marketing and Distribution Agreement

Dated As Of

September 29, 2006

Between

Inverness Medical Innovations, Inc.

And

Chembio Diagnostic Systems, Inc.

Table of Contents

Non-Exclusive License, Marketing and Distribution Agreement

PREAMBLE

This Non-Exclusive License, Manufacturing and Distribution Agreement (the "**Agreement**") is made as of September 29, 2006 ("**Effective Date**"), by and between **Chembio Diagnostic Systems, Inc.**, a **Delaware** corporation having its principal place of business at 3661 Horseblock Road, Medford, New York 11763, ("**Chembio**") and **Inverness Medical Innovations, Inc.**, a Delaware corporation having its principal place of business at 51 Sawyer Road, Waltham, MA 02453 ("**Inverness**").

RECITALS

Certain capitalized terms used in these Recitals but not defined in the Preamble or upon first use are defined in Section 1.1.

Inverness, among other activities, is in the business of developing, marketing and selling products used to diagnose various diseases, and owns or has rights to grant licenses to a number of patents pertaining to disease diagnosis, including the Inverness Lateral Flow Patents.

Chembio, among other things, is in the business of developing, marketing and selling products used to diagnose various diseases, and has designed and developed the Licensed Products, which Chembio manufactures and sells throughout the world.

During the Term, Inverness wishes to license the Inverness Lateral Flow Patents to Chembio for the purpose of allowing Chembio to manufacture and sell the Licensed Products, and Chembio wishes to obtain such licenses to the extent such licenses are necessary.

During the Term, Inverness wishes to be a non-exclusive marketer and distributor of the Licensed Products worldwide, and Chembio wishes to grant Inverness the non-exclusive right to market and sell the Licensed Products worldwide.

In addition, the Parties are simultaneously entering into certain other agreements, licenses and covenants, including an agreement between the Parties and StatSure Diagnostic Systems, Inc. ("**SDS**").

NOW, THEREFORE, in consideration of the premises and the mutual promises, covenants and conditions hereinafter set forth, the receipt and adequacy of which are hereby acknowledged, Chembio and Inverness hereby agree as follows:

1. **Definitions**.

1.1. **Certain Definitions**

. For purposes of this Agreement, in addition to the terms that are defined on first use herein, the following terms shall have the following meanings:

(a) The "**Act**" shall mean the Federal Food, Drug and Cosmetic Act, as amended, and all relevant federal regulations pertaining thereto.

(b) "**Affiliate**" shall mean any Person that controls, is controlled by, or is under common control with a Party hereto. For purposes of this definition, "control" shall mean (i) in the case of corporate entities, direct or indirect ownership of a majority of the stock or shares having the right to vote for the election of directors, and (ii) in the case of non-corporate entities, direct or indirect ownership of a majority of the equity interest with the power to direct the management and policies of such non-corporate entities.

(c) **"Audit"** shall mean examination of each and every document relating to the licenses and rights granted herein, including but not limited to books, records, agreements, communications, shipping records, purchase orders, invoices, credit memos and record of payments received or made, such audit to be conducted by a nationally recognized public accounting firm.

(d) "**Challenge**" means to challenge the validity or enforceability of any Patent Rights, including without limitation by (i) filing a declaratory judgment action in which Patent Rights are alleged to be invalid or unenforceable; (ii) citing prior art pursuant to 35 U.S.C. Sec. 301, making a request for re-examination of Patent Rights pursuant to 35 U.S.C. Sec. 302 and/or 311, or provoking or becoming party to an interference with an application for Patent Rights pursuant to 35 U.S.C. Sec. 135; or (iii) filing or commencing any opposition, cancellation, nullity or similar proceedings against Patent Rights in any country.

(e) "**Chembio IP**" shall mean all proprietary rights and Intellectual Property Rights, including but not limited to Patent Rights, owned or Controlled by Chembio, which are necessary or useful for, or would be infringed by, the use, sale, distribution, import or export of the Licensed Products, whether now in existence or in the future, including but not limited to those as listed on Schedule A.

(f) "**Chembio Listed Patents**" shall mean the patents and patent applications listed on Schedule A.

(g) "**Chembio Trademarks**" shall mean the Trademarks listed on Schedule B.

(h) "**Confidential Information**" shall mean all Technology and ideas and information of any kind, whether in written, oral, graphical, machine-readable or other form, whether or not marked or identified as confidential or proprietary, which are transferred, disclosed or made available by any Party hereto to any other.

(i) **"Control"** or **"Controlled by"** shall mean, in the context of Patent Rights or other Intellectual Property Rights, possession of the ability on the part of a Party to grant access to or a license or sublicense as provided for herein without violating the terms of any agreement or other arrangement with any Third Party (other than an Affiliate) existing at the time such Party would be required hereunder to grant another Party such access or license or sublicense.

(j) **"Costs"** shall mean Chembio's costs, calculated in accordance with GAAP and attributed on a per-unit-of-Licensed Product basis, of manufacturing and shipping the Licensed Products provided to Inverness hereunder, obtaining and maintaining regulatory approvals for the Licensed Products, and obtaining and maintaining licenses from any Third Parties to manufacture, market, distribute or sell the Licensed Products and the amortization over the period during which Licensed Products are sold to Inverness of the cost in procuring such licenses. The term "Costs" shall also include costs associated with (1) compliance, (2) complaint handling and (3) quality control. Such costs shall be restricted to costs incurred by Chembio after the Effective Date, except that license fees paid for those licenses listed in Schedule C obtained prior to the Effective Date will be amortized as set forth in Schedule C over the period during which Licensed Products are sold to Inverness.

(k) **"Developing Countries"** means those countries listed on Schedule G.

(l) **"Dipstick Product"** means Chembio's HIV 1/2 STAT PAK(TM) Dipstick product.

(m) "**Distributor**" shall mean any Third Party, other than an Affiliate of Inverness, to which Inverness or Chembio grants a limited sublicense under the rights granted Inverness under Section 2.2 or granted Chembio under Section 2.1 for the purpose of reselling or distributing Licensed Products.

(n) "**Exploit**" or "**Exploitation**" shall mean to sell, offer for sale, import, export, transport, register, distribute, promote and market, together with other activities typically associated with maximizing the market penetration, profit margins and commercialization of a diagnostic medical product.

(o) "**FDA**" means the U.S. Food and Drug Administration.

(p) "**First Commercial Sale**" shall mean, with respect to a product, the first sale to any non-Affiliate.

(q) "**GAAP**" means United States Generally Accepted Accounting Principles, as applicable to the Party in question.

(r) "**GMP**" means current Good Manufacturing Practices as promulgated by the FDA.

(s) "**Intellectual Property Rights**" shall mean (i) Patent Rights; (ii) rights associated with works of authorship including copyrights, copyright applications and copyright registrations; and (iii) rights relating to the protection of trade secrets, know-how and Confidential Information, but shall not include any rights to trade marks,

trade names, or other distinctive brand names or logos.

(t) "**Inverness Lateral Flow Patents**" shall mean any Patent Rights in the patents and patent applications identified on Schedule E.

(u) "**Inverness Trademarks**" shall mean the trademarks listed on Schedule F.

(v) "**Licensed Products**" shall mean (a) Chembio's veterinary tuberculosis and parvovirus products, products for the testing of Trypanasoma Cruzi, African Trypanasoma, human tuberculosis, Leishmaniasis, and Leptospirosis, as described on Schedule D; and (b) the Dipstick Product.

(w) **Net Sales**.

(i) "**Net Sales**" shall mean, with respect to any Licensed Product, the gross amount received by the seller or its Affiliates or permitted Sublicensees on bona fide sales of such Licensed Product to Third Parties, less the following items (to the extent the gross amount received by them otherwise reflects such items): (i) credits and allowances for price adjustment, rejection, recall or return of the Licensed Product; (ii) amounts for transportation, insurance, handling or shipping charges; (iii) taxes, duties and other governmental charges levied on or measured by the sale of the Licensed Product, but not franchise or income taxes of any kind whatsoever; (iv) quantity and other trade discounts, credits or allowances actually allowed and taken; (v) charge back payments and/or rebates for the Licensed Product provided to managed health care organizations, international organizations, or federal, state, local or other governments, including, in the United States, Medicare and Medicaid; or (vi) license fees, royalties or similar paid to Third Parties to allow the seller or its Affiliates to Exploit the relevant Licensed Product without infringement of Third Party (other than an Affiliate of the seller) Intellectual Property Rights. Net Sales shall not include any consideration received for demonstrations, test marketing, clinical trial purposes or compassionate or similar use. All of the amounts specified in the definition of Net Sales shall be determined from the books and records of seller of the Licensed Product and its Affiliates, maintained in accordance with GAAP, consistently applied.

(ii) **Bundling**. In the event that any particular Licensed Product is sold as part of a bundle or kit with products other than such Licensed Product, the Net Sales allocated to such Licensed Product shall be determined by multiplying the net selling price (that is, the gross selling price less such applicable deductions as are permitted in the calculation of Net Sales) of the bundle or kit by the fraction A ÷ (A + B) where A is the average selling price during the period in question in the country in question in quantities similar to the sale in question for the Licensed Product sold separately and B is the average selling price during the period in question in the country in question in quantities similar to the sale in question for the remaining products in the bundle or kit, when such products are sold separately from the Licensed Product (in each case as the average selling price is documented by the seller or its Affiliates or Sublicensees' records). In the event that any products contained in the bundle or kit are not sold separately, the Net Sales from sales of such bundle or kit allocated to Licensed Products shall be determined in a fair and equitable manner by mutual agreement of the parties.

(iii) **Sales to Distributors**. It is understood and agreed that all sales of Licensed Product by the seller, its Affiliates and permitted Sub-licensees to any Distributor shall be treated as Net Sales hereunder, and that subsequent sale of Licensed Product by any such Distributor shall not be treated as Net Sales hereunder.

(x) "**Party**" or "**Parties**" shall mean each of Inverness and Chembio (but not their Affiliates).

(y) "**Patent Costs**" shall mean the costs and expenses paid to outside legal counsel and other Third Parties, allocated in-house costs of legal counsel, and filing and maintenance expenses, incurred in connection with preparing, filing, prosecuting, obtaining and maintaining Patent Rights, including costs and expenses of patent interference, re-examination, reissue, opposition or similar proceedings.

(z) "**Patent Prosecution Action**" shall mean any and all actions that may be taken in connection with preparing, filing, prosecuting, obtaining and maintaining throughout the world patent protection for Patent Rights licensed hereunder, including patent applications and other related material submissions and correspondence with any patent authorities.

(aa) "**Patent Rights**" shall mean all patents, patent applications and inventions on which patent applications are filed and all patents issuing therefrom worldwide, all disclosures of inventions, together with any extensions, registrations, confirmations, reissues, continuations, divisionals, continuations, continuations-in-part, reexamination certificates, substitutions or renewals, supplemental protection certificates, term extensions (under applicable patent law or other law), provisional rights and certificates of inventions.

(bb) "**Person**" shall mean an individual, corporation, partnership, limited partnership, limited liability company, unincorporated association, trust, joint venture or other organization or entity, including a governmental authority.

(cc) "**QSRs**" means current Quality Systems Regulations as promulgated by the FDA.

(dd) "**Related Documents**" shall mean the Settlement Agreement and HIV Barrel Product Commercialization Agreement between SDS and Chembio, the License and Distribution Agreement between SDS and Inverness, the HIV Cassette License, Marketing and Distribution Agreement between Chembio and Inverness, and the HIV Barrel License, Marketing and Distribution Agreement between Chembio and Inverness.

(ee) "**Rest of the World**" means worldwide, excluding the United States.

(ff) **"Specifications"** shall mean the information contained in Schedule D regarding the Licensed Product and the together with any and all other related documentation or procedures in possession by Chembio that substantiate or support the information contained within Schedule D.

(gg) "**Sublicensee**" shall mean any sublicensee of any of the rights granted to Inverness under Section 2.2, other than an Affiliate or a Distributor.

(hh) "**Technology**" shall mean all techniques, inventions, practices, procedures, knowledge, improvements, designs, processes, protocols, compositions, products, methods, works of authorship, know-how, data, clinical data, preclinical data, research and creations (whether or not subject to protection by any Intellectual Property Rights).

(ii) "**Third Party**" shall mean any Person other than Inverness or Chembio.

(jj) "**United States**" means the United States of America and its territories and possessions, including without limitation Puerto Rico and the U.S. Virgin Islands.

(kk) "**Valid Claim**" shall mean a claim of an issued and unexpired patent that has not been permanently revoked, held unenforceable or invalid by a final, nonappealable decision of a court or other governmental agency of competent jurisdiction (the term "final, nonappealable decision" includes decisions that become final

through exhaustion of all permissible avenues for rehearing or review by a superior tribunal and decisions that become final through expiration of the time allowable for appeal), or admitted by the patentee to be invalid or unenforceable through reissue, reexamination, disclaimer or otherwise.

1.2. **Additional Definitions**

. Certain additional capitalized terms are defined below in the body of this Agreement.

2. **License Grants.**

2.1. **Inverness License**

. Inverness, on and subject to the terms and conditions contained herein, hereby grants to Chembio and Chembio hereby accepts from Inverness, a non-transferable, non-exclusive, royalty-bearing license, under the Inverness Lateral Flow Patents, for the Term to manufacture and to Exploit the Licensed Products worldwide, provided however that Chembio shall have no license to Exploit the Dipstick Product in the United States, but shall have a license to export the Dipstick Product from the United States (the "**License**"). The License may not be sublicensed. Chembio shall manufacture the Licensed Products itself or may subcontract the manufacture of the Licensed Products to the extent permitted by applicable law, but may not sublicense such manufacturing right. If Chembio subcontracts the manufacture of the Licensed Products, Chembio shall enter into a written agreement with any such manufacturer consistent with the terms of this Agreement and shall remain primarily liable for breach of this Agreement by the manufacturer. The License shall be deemed to include a grant to Chembio of the right to Exploit through any Affiliate of Chembio and through Distributors of Chembio or any Affiliate of Chembio.

(a) Inverness and Chembio acknowledge that the license in this Section 2.1 is subject to the limitation that the Charlton Lateral Flow Patents (as described on Schedule E) are not licensed for the Over-The-Counter market; such Charlton Lateral Flow Patents are licensed only with respect to products for sale through any channels for use by licensed professional health-care providers (including hospitals, physicians acting as such and licensed professional health-care centers).

(b) Subject to the obligations contained in this Agreement or any Related Document to the contrary, the parties acknowledge that: (a) the Licensed Products may be divided into the "**Existing Products**", meaning the Licensed Products as they exists on the Effective Date, and the "**Future Products**", meaning any Licensed Products not in existence on the Effective Date, and any modified or future versions of the Existing Products made after the Effective Date; and (b) the Inverness Lateral Flow Patents may be divided into "**Current Lateral Flow Patents**" and "**Future Lateral Flow Patents**". The "**Current Lateral Flow Patents**" are: (i) the patents and patent applications on Schedule E; (ii) any continuations and divisionals of the patents and patent applications on Schedule E; (iii) any continuations-in-part of the patents and patent applications on Schedule E to the extent the claims thereof are directed to subject matter specifically described in (i) and (ii) above; and (iv) any foreign counterparts of the patents and patent applications described in (i), (ii) and (iii) above. The "**Future Lateral Flow Patents**" means any continuation-in-part of the Current Lateral Flow Patents not described in (iii) above, and any foreign counterpart of such continuation-in-part. All licenses granted by Inverness in this Agreement grant licenses to the Current Lateral Flow Patents with respect to both Existing Products and Future Products. The licenses granted by Inverness in this Agreement grant licenses to Future Lateral Flow Patents: (a) for Existing Products; and (b) for Future Products, but only with respect to claims in the Future Lateral Flow Patents that are infringed by the making, using, selling or importing of any Existing Product. Otherwise, Inverness grants no right or license to any Future Lateral Flow Patents under this Agreement, including without limitation any license to any Future Lateral Flow Patent except as described in the foregoing sentence.

2.2. **Non-Exclusive Right to Purchase and Exploit**

. Chembio, on and subject to the terms and conditions contained herein, hereby grants to Inverness and Inverness hereby accepts from Chembio the non-exclusive right to purchase from Chembio and to Exploit, worldwide, during the Term, the Licensed Products (other than the Dipstick Product) and may do so only utilizing Inverness Trademarks. This right shall be deemed to include a grant to Inverness of the right and license to sell through any Affiliate of Inverness and through Distributors of Inverness or of any Affiliate of Inverness. Chembio acknowledges that Inverness is under no obligation to purchase or Exploit any or all of the Licensed Products.

2.3. **Patent Marking**

. Chembio will include the patent numbers of the Inverness Lateral Flow Patents and indicate Inverness' and its licensors ownership of such patents on the packaging for all Licensed Products.

2.4. **SDS Access**

. It is understood by the Parties that SDS shall be entitled to receive copies of this agreement and any amendments if and when effected.

2.5. **Termination of Licenses Upon Challenge of Validity**

. In all jurisdictions where such agreement is permitted by law, and to the maximum extent so permitted: (a) Chembio agrees not to Challenge any Patent Rights of Inverness or its Affiliates in the Inverness Lateral Flow Patents listed on Schedule E; and (b) Inverness agrees not to Challenge the Patent Rights in the Chembio Listed Patents. In addition to the foregoing, and whether or not the foregoing prohibition is permissible or otherwise enforceable, in the event that Inverness Challenges any Patents Rights in any Chembio Listed Patents, or Chembio Challenges any Patent Rights in any Inverness Lateral Flow Patents, the Party whose right is Challenged shall have the right, in its sole discretion and immediately on written notice, to terminate this Agreement for cause.

3. **Royalties and Payments.**

3.1. **Exclusive Payment Arrangements**

. This Article 3 describes the manner in which the Parties will share revenues derived from the sale of Licensed Products. No other fees, payments or royalties are due from any Party to any other Party with respect to the licenses and rights set forth in this Agreement.

3.2. **Pricing of Licensed Products**

. Subject to the limitations set forth in this Article 3, each Party that sells any Licensed Products hereunder may set the prices at which it sells such Licensed Products in its sole and absolute discretion.

3.3. **Inverness Sale of Licensed Products - Division of Net Sales**

. Inverness shall retain 35% of Net Sales of Licensed Products made by Inverness and its Affiliates in Developing Countries, and 50% of Net Sales of Licensed Products made by Inverness and its Affiliates in the Rest of the World. For the purposes of this paragraph, Net Sales of Licensed Products are "made" in a particular region, such as a Developing Country, when a sale is made to a Distributor that is located in such region. The remaining percentage of Net Sales (the "**Chembio Share**") shall be paid to Chembio.

3.4. **Minimum Price**

. Notwithstanding Sections 3.2 and 3.3, Chembio shall be under no obligation to supply Licensed Products to Inverness for less than 115% of Costs. As such, in the event that the Chembio Share of Net Sales for any Licensed Product in any particular country or countries is less than 115% of Costs, Chembio may, by written notice, require Inverness not to sell such Licensed Product in such country.

3.5. **Payment of Cost of Licensed Products Sold by Inverness**

. Inverness shall pay Chembio its Costs of Licensed Products in accordance with the following procedure:

(a) Prior to Inverness' order for any Licensed Product, Chembio shall provide to Inverness a reasonable, good faith estimate of the per-unit amount representing Chembio's Cost for such Licensed Product (("**Deemed Cost**"), and Inverness shall provide to Chembio the estimated per-unit amount representing Inverness' Net Sales for such Licensed Product ("**Deemed Price**"). The initial Deemed Cost and Deemed Price shall apply for the purposes of sub-paragraph (b) below from Inverness' initial order until the end of the calendar quarter immediately following the calendar quarter in which the initial order was placed. For the remainder of the Term, the Deemed Cost shall be adjusted each quarter based on the actual Cost of Licensed Products in the latest quarter for which actual Costs have been reported pursuant to Section 3.8

(b) Each shipment of Licensed Products by Chembio shall be accompanied by an invoice, in a form reasonably satisfactory to Inverness, for the Licensed Products in the shipment at the then-current Deemed Cost (as hereinafter defined). Within thirty (30) days of receipt of a duly issued invoice for Licensed Product shipped by Chembio in accordance with this Agreement, Inverness shall pay Chembio such Deemed Cost and any additional Chembio Share.

(c) Any adjustments to actual Costs for overpayments or underpayments made by Inverness shall be made pursuant to the quarterly accountings set forth in Section 3.8. For purposes of these calculations, Cost of Licensed Product will be matched to sales on a FIFO basis.

3.6. **Royalties Payable by Chembio on Inverness Lateral Flow Patents**

. Chembio shall pay Inverness royalties of five percent (5%) of Net Sales of Licensed Products made by Chembio and its Affiliates in Developing Countries, and eight and one-half percent (8.5%) of Net Sales of Licensed Products made by Chembio and its Affiliates in the Rest of the World excluding Developing Countries (provided that no Dipstick Products are licensed for the United States). For the purposes of this paragraph, sales of Licensed Products are "made" in a particular region, such as a Developing Country, when a sale is made to a Distributor that is located in such region; provided, however that Inverness reserves the right to charge the higher royalty rate if it can reasonably show that a Distributor located in a Developing Country is selling Licensed Products to an end-purchaser located in a non-Developing Country, and Chembio shall have the right to pay the lower royalty rate if it can reasonably show that a Distributor located in a non-Developing Country is selling Licensed Products to an end-purchaser in a Developing Country.

(a) No royalties shall be payable unless the Licensed Product infringes a Valid Claim of the Inverness Lateral Flow Patents in the country in which the Licensed Product is manufactured or the country in which the Licensed Product is sold.

(b) Only one royalty shall be due Inverness for any Licensed Product regardless of the number of Valid Claims of the Inverness Lateral Flow Patents that would be infringed.

(c) The obligation to pay royalties on Net Sales of Licensed Product shall be imposed only once with respect to each Licensed Product, even if such Licensed Product is sold more than once in the course of its transfer to the ultimate end-user.

(d) The above royalties on Licensed Products are not payable by Chembio with respect to Licensed Products distributed by Inverness, for which the revenue sharing arrangements set forth in Section 3.3 are the sole and exclusive payment arrangements between the parties.

3.7. **Payment by Inverness for Samples**

. Subject to Inverness' review of and acceptance of Chembio's Costs, Inverness shall pay Chembio 110% of the Costs associated with the manufacture by Chembio of Licensed Products that are used by Inverness for demonstrations, testing, clinical trials, sample and compassionate or similar use.

3.8. **Reporting and Calculation of Payments**.

(a) For any calendar quarter for which payments under Section 3.3 are due to Chembio, Inverness shall deliver to Chembio, within sixty (60) days after the end of such calendar quarter, reasonably detailed written accountings of Net Sales of the Licensed Products during such calendar quarter. Such report shall indicate Net Sales on a country-by-country and Licensed Product-by-Licensed Product basis (and not on an order-by-order basis).

(b) Within seventy-five (75) days of the end of each calendar quarter during the Term, Chembio shall deliver to Inverness a complete and accurate accounting of all Costs and a determination of the cost per unit for all Licensed Products sold to Inverness pursuant to this Agreement. The Costs reflected shall be the basis for payments to Chembio to be made by Inverness pursuant to Section 3.3. The per-unit allocation of Costs to products sold shall be determined on a FIFO basis. Cost so determined shall remain in effect until the next such accounting.

(c) Within ninety (90) days after the end of any calendar quarter for which reports have been delivered pursuant to sub-paragraphs (a) and (b) above, Inverness shall deliver Chembio a report showing the calculation of the amounts due to Chembio pursuant to Section 3.3, and any payments to be made hereunder. Such payments may be payable from either Inverness or Chembio, depending on whether Chembio has been underpaid or overpaid pursuant to the procedure set forth in Section 3.4, and shall be made no later than seven days after delivery of such report. With respect to Net Sales invoiced in a currency other than United States Dollars, Net Sales and royalties payable shall be expressed in their United States dollar equivalent, calculated using an average exchange rate for buying United States dollars published by The Wall Street Journal during the calendar quarter. All payments due to Chembio hereunder shall be made from the United States in United States dollars by transfer to such bank account as Chembio may designate.

(d) For any calendar quarter for which payments are due under this Agreement to Inverness, Chembio shall deliver Inverness, within sixty (60) days after the end of such calendar quarter, reasonably detailed written accountings of Net Sales of the Licensed Products during such calendar quarter. Such report shall indicate Net Sales on a country-by-country and Licensed Product-by-Licensed Product basis, and the calculation of the royalty due to Inverness, and any payments to be made hereunder. When Chembio delivers such accountings, it shall also deliver all payments due under this Agreement to Inverness for such calendar quarter. With respect to Net Sales invoiced in a currency other than United States Dollars, Net Sales and royalties payable shall be expressed in their United States dollar equivalent, calculated using an average exchange rate for buying United States dollars published by The Wall Street Journal during the calendar quarter. All payments due from Chembio hereunder shall be made from the United States in United States dollars by transfer to such bank account as Inverness may designate.

(e) Chembio shall keep complete and accurate records of the latest two (2) years of Costs of Licensed Products sold to Inverness hereunder. For the sole purpose of verifying Costs to be reimbursed to Chembio, Inverness shall have the right once per calendar year to retain an independent certified public accountant, selected by Inverness and reasonably acceptable to Chembio, to conduct an Audit in the location(s) where such records are maintained upon twenty (20) days prior written notice and during regular business hours, with all information disclosed being deemed Confidential Information hereunder. The cost of the Audit shall be paid by Inverness. Such Audit shall be completed within fifteen (15) business days, subject to extension by the auditor if the auditor reasonably determines in good faith that data or information it requires is not available and identifies the data or information required. Results of such review shall be made available to Chembio and Inverness. Inverness shall recalculate the payments made to the Parties and any Party overpaid shall promptly reimburse any underpaid Party. If a recalculation of Costs is equal to or greater than five (5%) percent of the correctly-calculated Costs, Inverness shall be entitled to have Chembio pay the reasonable out-of-pocket costs incurred by Inverness to retain such independent certified public accountant to conduct such review.

(f) Each Party ("Payer") shall keep complete and accurate records of the latest two (2) years of sales of Licensed Products to which royalties or shares of Net Sales to the other Party ("Payee") attach hereunder. For the sole purpose of verifying payments due to a Payee, said Payee shall have the right, once per calendar year, to retain an independent certified public accountant, selected by said Payee and reasonably acceptable to the Payer, to conduct an Audit in the location(s) where such records are maintained upon twenty (20) days prior written notice and during regular business hours, with all information disclosed being deemed Confidential Information of the Payer. Such Audit shall be completed within fifteen (15) business days, subject to extension by the auditor if the auditor reasonably determines in good faith that data or information it

requires is not available and identifies the data or information required. Whichever Party requests the Audit shall bear the costs thereof. Results of such review shall be made available to the Payer and the relevant Payee. If the Audit reflects an underpayment of amounts due, such underpayment shall be promptly remitted to the appropriate Payee by the Payer. If the underpayment is equal to or greater than five (5%) percent of the amount that was otherwise due, the Payee shall be entitled to have the Payer pay the reasonable out-of-pocket costs incurred by the Payee to retain such independent certified public accountant to conduct such review.

(g) Whenever reports upon which payments are based are to be made by any Party, they shall be certified as correct by the Chief Financial Officer of the Party. In addition, to the extent required of a Party by the provisions of the Sarbanes-Oxley Act, each of the Parties shall make available information as may be required for proper certification in accordance with Section 404 and any rules promulgated thereunder.

4. **Regulatory and License Matters**.

4.1. **Facility Registration/Inspections**

. Chembio shall, if it has not done so prior to the Effective Date, register, at its expense, with FDA, in accordance with the Act, each establishment in which it intends to manufacture any Licensed Product and maintain, at its expense, all such establishment registrations during the term of this Agreement. Chembio shall permit FDA and Inverness to inspect each such establishment for purposes of verifying Chembio's compliance with the Act, including GMPs and QSRs, and for purposes of verifying that all items being manufactured by Chembio for sale to Inverness hereunder are being manufactured in accordance with the applicable Specifications; Inverness' participation in such inspections shall be at Inverness' cost. Any such inspection by Inverness shall be conducted upon reasonable advance notice to Chembio during the normal business hours of the facility to be inspected. Chembio acknowledges and agrees that no inspection by Inverness pursuant to this Section 4.1 shall relieve or diminish any of Chembio's obligations hereunder.

4.2. **Regulatory Filings**

. Chembio shall be responsible for (1) obtaining and maintaining, and (2) paying for the obtaining and maintaining of, regulatory approvals required for the lawful distribution and sale of Licensed Products in the applicable territories. So long as Chembio is in compliance with all applicable regulatory requirements for the Licensed Product in the territories that it chooses to market such Licensed Products, nothing herein shall require Chembio to obtain or maintain regulatory approvals in any jurisdiction if Chembio, in its sole discretion, deems that it is not commercially reasonable to do so.

5. **Manufacture and Sale**.

5.1. **Chembio Efforts**

. Chembio shall use commercially reasonable efforts to manufacture the Licensed Product and to supply all of Inverness' requirements for such product, in accordance with the published specifications for each such Licensed Product (the "**Specifications**") and the supply requirements and limitations set forth in this Section 5. In the event of any supply constraints which prevent Chembio from supplying all of Inverness' requirements for Licensed Products, Chembio shall treat Inverness no less favorably than other distributors of Licensed Products and shall ensure that Inverness receives at least its pro rata share of available products (based on Inverness' average pro rata share of sales over the four (4) most recent calendar quarters).

5.2. **Forecasts**

. During the Term, Inverness shall provide Chembio, on a quarterly basis, with forecasts of Inverness's anticipated orders for the Licensed Product during the succeeding three (3) quarters. The initial forecast shall be produced and delivered by Inverness to Chembio promptly after the Effective Date. Chembio hereby acknowledges and agrees that Inverness shall have the right to revise any quarterly forecast issued pursuant to this Section at any time upon notice given to Chembio not less than three months before the forecast delivery date for any products; any forecasts for delivery less than three months from the forecast date shall be binding on both parties. Inverness shall issue purchase orders and accept delivery of not less than ninety (90%) percent of the forecast quantity. Chembio shall not be required to timely deliver more than one hundred and twenty-five (125%) percent of the forecast quantity, but shall deliver not less than 100% of the quantity required by Inverness' binding forecasts.

5.3. **Purchase Orders**

. All sales and purchases of the Licensed Product, if any, hereunder shall be initiated pursuant to Inverness's purchase order for the same placed with Chembio. Such purchase orders shall include relevant details of the order such as quantity, the current Costs of each Licensed Product, destination, billing and shipping information, and requested delivery date(s) (a "**Purchase Order**"). Chembio shall accept Purchase Orders by written notice to Inverness within five (5) days of receipt. In the event that Chembio cannot comply with a delivery date requested by Inverness in any Purchase Order, Chembio may request an alternative delivery date, which shall be not more than forty-five (45) days after the date requested by Inverness. Any terms and conditions contained in any Purchase Order or written acceptance of a Purchase Order, invoice or other writing delivered by Chembio to Inverness or by Inverness to Chembio that are inconsistent with the terms and conditions of this Agreement shall be null and void and of no effect unless agreed to in a writing executed by an authorized representative of Inverness and Chembio. At any time up to ten (10) days prior to the delivery date set forth in any Purchase Order, Inverness may issue an alteration to a Purchase Order in order to (i) change a location for delivery, (ii) correct typographical or clerical errors, or (iii) reschedule a delivery. In such event, Inverness shall reimburse Chembio for all reasonable resulting costs incurred by Chembio and notified by Chembio to Inverness within seven (7) days after alteration of the purchase order.

5.4. **Shipment Terms**

. Licensed Product ordered by Inverness shall be shipped FOB, point of manufacture, with the carrier and to the destination specified in the Purchase Order.

5.5. **Acceptance**

. Within twenty (20) days after receipt of any Licensed Products, Inverness shall inspect and, in its discretion, test the Licensed Products to determine whether they conform in all material respects to the Specifications. In the event an Licensed Product does not so conform, Inverness may within such twenty (20) day period (i) continue to test the Licensed Product, or (ii) return the non-conforming Licensed Product to Chembio, at Chembio's expense, and any amounts paid by Inverness for the Licensed Product returned shall be refunded by Chembio to Inverness. If Inverness does not return a non-conforming Licensed Product within such twenty (20) day period, it is deemed accepted.

5.6. **Inverness Responsibilities; Rights**

. In connection with its distribution, marketing and sales of the Licensed Products (as permitted in this Agreement), Inverness shall provide all sales force (including, without limitation, sales administration and training), order entry, customer service, reimbursement management, medical affairs, medical information, marketing (including all advertising and promotional expenditures), warehousing, physical distribution, invoicing, credit and collections, production forecasting and other related facilities and services as it deems necessary or desirable for such distribution, marketing and sales.

6. **Trademarks**

6.1. **Trademark License**

. Inverness shall Exploit the Licensed Products (other than the Dipstick Product) under the Inverness Trademarks. Accordingly, Chembio hereby grants Inverness, to the extent that Chembio possesses such rights, a worldwide, royalty-free license during the Term to use the Chembio Trademarks but only for the purpose of indicating that the Licensed Products are manufactured by Chembio for Inverness. All such use of the Chembio Trademarks shall inure to the benefit of Chembio. Inverness hereby grants Chembio a non-exclusive, non-transferable license to use the Inverness Trademarks, but only for the purpose of labeling and packaging the Licensed Products for sale to Inverness in the event that Inverness elects to mark the Licensed Products with Inverness Trademarks. All such use of the Inverness Trademarks shall inure to the benefit of Inverness. Neither party shall use or alter such marks in a manner which may jeopardize or diminish the other party's rights to use them, and all notices of rights therein and all notices of any patent and/or patent pending rights to the Licensed Products shall be clearly designated in all written materials in which such marks are used.

6.2. **Compliance with Law; Registration**

. Each Party, in using the other Party's trademarks, shall use such marks and/or names only in such manner as will comply with the provisions of applicable trademark laws. Any and all trademark applications which are filed in any jurisdiction for a Party's trademarks shall be filed by that Party and that Party shall bear all costs incurred in connection with such trademark applications and registrations. No trademark costs incurred by Chembio shall be included in Costs.

6.3. **Termination**

. The licenses granted under Section 6.1 shall terminate upon any termination of this Agreement, and thereafter neither party shall use the other party's trade names, service marks, or trademarks except in connection with sale by Inverness of Licensed Products purchased prior to the termination of this Agreement.

6.4. **Labeling**

. Inverness shall develop, produce and provide all labeling for such Licensed Product, subject to Chembio's approval, such approval not to be unreasonably withheld. All materials referring or relating to the Licensed Products shall include the following in legible font: "Manufactured by Chembio Diagnostic Systems, Inc., Medford, NY for Inverness Medical Innovations under [patents no.s of Inverness Lateral Flow Patents] owned or licensed by Inverness Medical Innovations, Inc.".

7. **Prosecution and Enforcement of Licensed Intellectual Property**.

7.1. **Prosecution**

. The owner or Controller of Intellectual Property Rights (the "**Patent Owner**") (for example, Inverness in the case of the Inverness Lateral Flow Patents and Chembio in the case of the Chembio IP) shall have the sole right to prepare, file, prosecute, obtain and maintain throughout the world, and otherwise take all Patent Prosecution Actions with respect to its Intellectual Property Rights as such Patent Owner shall deem to be appropriate in its discretion. Each Patent Owner shall pay all Patent Costs incurred by it in connection with the foregoing activities and such Patent Costs shall not be deemed Costs hereunder. If it becomes necessary or desirable, the other Parties shall fully cooperate with the Patent Owner, at the Patent Owner's request and expense, in connection with all Patent Prosecution Actions; provided that no Party shall be obligated to provide such cooperation if, in its reasonable business judgment, such cooperation would be adverse to its interests outside this Agreement.

7.2. **Enforcement of Licensed Patents**

. The Patent Owner shall have the sole right to enforce and defend any of its Intellectual Property Rights licensed hereunder, at its own expense. Notwithstanding the foregoing, each of the Parties shall inform the other Parties promptly in writing of any alleged infringement, misuse or misappropriation by any Person of any Intellectual Property Rights licensed hereunder that affects the Exploitation of Licensed Products or other products licensed hereunder, and the Parties shall reasonably consult with each other with respect to the strategy to resolve the alleged infringement, misuse or misappropriation. In the event that a Patent Owner shall initiate an infringement action or defend an action in accordance with this Section, the other Parties shall fully cooperate and supply such assistance as reasonably requested by the Patent Owner; provided that no Party shall be obligated to provide such cooperation if, in its reasonable business judgment, such cooperation would be adverse to its interests outside this Agreement.

8. **Confidentiality**.

8.1. **Limited Disclosure and Use**

. Each of Inverness and Chembio shall hold in confidence any Confidential Information disclosed by any other Party or otherwise obtained by such Party from any other as a result of this Agreement, and each of Inverness and Chembio shall protect the confidentiality thereof with the same degree of care that it exercises with respect to its own information of a like nature, but in no event less than reasonable care. Without the prior written consent of the disclosing Party, a receiving Party shall not use, disclose, or distribute any Confidential Information, in whole or in part, except as required to perform such Party's obligations or exercise such Party's rights hereunder. Access to the disclosing Party's Confidential Information shall be restricted to the receiving Party's employees and agents, who, in each case, need to have access to carry out a permitted use and are bound in writing to maintain the confidentiality of such Confidential Information.

8.2. **Exceptions**

. The obligations set forth in Section 8.1 shall not apply to any portion of the Confidential Information that the receiving Party can demonstrate by legally sufficient evidence: (i) now or hereafter, through no act or failure to act on the part of the receiving Party, is or becomes generally available; (ii) is known to the receiving Party at the time of receiving such Confidential Information and not subject to an obligation of confidentiality to a Third Party; (iii) is hereafter furnished to the receiving Party by a Third Party as a matter of right (and without violating any agreement with the disclosing Party) without restriction on use or disclosure; or (iv) is independently developed by the receiving Party without use of any Confidential Information received from the other Party. In addition, each receiving Party may disclose Confidential Information to the extent such disclosure is reasonably necessary to protect Intellectual Property Rights to which such Party has a license hereunder, to prosecute or defend litigation, to comply with applicable law or regulation, to obtain necessary or desirable regulatory approvals, to respond to a valid order of a court or other governmental body or any political subdivision thereof, or to conduct preclinical or clinical trials, provided that, other than with respect to disclosure for protecting Intellectual Property Rights, the receiving Party shall use reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed.

8.3. **Use of Name; Disclosure of Terms of the Agreement**

. Except as authorized in Section 6 hereof or otherwise required by applicable law, regulation or the rules of any securities exchange on which such Party's securities are listed, no Party shall use the names of the other Parties in any publicity or advertising without the prior written approval of the other Parties, except that any Party may disclose that they have entered into this Agreement. Except as may be required by applicable law, regulation or the rules of any securities exchange on which such Party's securities are listed, no Party shall disclose any terms or conditions of this Agreement without the prior written consent of the other Parties, provided that a Party may disclose such terms and conditions to any Third Party with whom such Party has entered into or proposes to enter into a business relationship (including any transaction that would result in a permitted assignment in accordance with the terms and conditions of Section 13.11), provided any such Third Party is informed of the confidentiality restrictions herein with respect to such terms and conditions and agrees to abide by such restrictions.

8.4. **Effect of Termination**

. Each Party shall, upon termination of this Agreement, immediately discontinue use of the other's Confidential Information. Within a reasonable time after termination of this Agreement, but in no event later than thirty (30) days thereafter, all materials containing such Confidential Information shall be returned by the receiving Party or (with the disclosing Party's prior written consent) destroyed.

8.5. **Survival**

. The confidentiality obligations set forth in this Section 8 shall survive any termination or expiration of this Agreement in perpetuity .

9. **Representations; Warranties**.

9.1. **Corporate Power**

. Each Party represents to the other Parties that it has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof. Each Party represents to the other that this Agreement constitutes a valid and binding agreement, enforceable against it in accordance with its terms.

9.2. **No Default or Violation**

. Each Party represents and warrants to the other Parties that the execution, delivery and performance of this Agreement does not (i) violate or require any registration, qualification, consent, approval, or filing under, (1) any law, statute, ordinance, rule or regulation, or (2) any judgment, injunction, order, writ or decree of any court, arbitrator, or governmental entity by which such Party or any of its assets or properties may be bound or (ii) conflict with, require any consent, approval, or filing under, result in the breach or termination of any provision of, constitute a default under, result in the acceleration of the performance of any obligations under, result in the vesting or enhancement of any other Person's rights under, or result in the creation of any lien upon any of such Party's properties, assets, or businesses pursuant to (x) its organizing documents or By-Laws or (y) any material indenture, mortgage, deed of trust, license, permit, approval, consent, franchise, lease, contract, or other instrument or agreement to which such Party is a Party or by which such Party or any of such Party's properties or assets is bound.

9.3. **Licensed Intellectual Property**

. Each Party licensing any Intellectual Property Rights (a "**Licensor**") to any other Party hereunder (a "**Licensee**") represents and warrants to each such Licensee that: (a) it has the full right, title and authority to grant to Licensee the licenses granted hereunder; and (b) to the best of the Licensor's knowledge and except as otherwise disclosed to the Licensee, all such licensed Patent Rights existing as of the Effective Date are valid and enforceable, and all patents, if any, issuing on any of the pending patent applications of the Patent Rights existing as of the Effective Date will be valid and enforceable. Inverness represents and warrants that the Inverness Lateral Flow Patents constitute all Patent Rights claiming lateral flow technology that Inverness has the right to sublicense.

9.4. **Regulatory Matters**

. Chembio represents and warrants that, with respect to the manufacture of the Licensed Products, Chembio will comply with the requirements of the Act, and to the best of its knowledge, all other applicable federal and state laws.

9.5. **Product Quality**

. Chembio represents and warrants that:

(a) Each unit of Licensed Product sold to Inverness hereunder shall be manufactured in accordance with and shall comply, at the time of delivery to Inverness, in all material respects with the applicable Specifications therefor, shall perform as intended in all material respects, and shall otherwise be free from defects in material and workmanship; and each unit of Licensed Product sold to Inverness hereunder will not, at the time of delivery, be adulterated or misbranded within the meaning of the Act or within the meaning of any jurisdiction in which the definitions of misbranding and adulteration are substantially the same as in the Act, nor will any such unit of Licensed Product, at the time of delivery to Inverness, be an article which may not, under the Act, be introduced into interstate commerce.

(b) In the event any unit(s) of Licensed Product does not conform with a warranty set forth in Section 9.5(a) applicable thereto, Inverness or an Affiliate of Inverness may return such unit(s) of Licensed Product within twenty (20 days of its receipt to Chembio and, in the event Inverness or an Affiliate of Inverness does so, Chembio, within thirty (30) days of its receipt of the return, shall either; (a) refund or credit Inverness's account in an amount equal to the purchase price paid by Inverness for such unit(s) of non-conforming Licensed Product, as the case may be, plus freight and insurance charges incurred by Inverness and/or its Affiliate incident to the original and return shipment, as documented by Inverness, or (b) replace, without charge, the non-conforming unit(s) of Licensed Product, as the case may be, with an equivalent number of like unit(s) Licensed Product, as the case may be, conforming with the applicable warranties set forth in Section 9.5(a) and refund or credit Inverness's account in an amount equal to said original and return freight and insurance charges incurred as documented by Inverness. The cost of returned units and freight and insurance charges hereunder shall not be included in Costs.

9.6. **Exclusion of Other Representations and Warranties**

. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NO PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY REPRESENTATIONS OR WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT. NO PARTY WARRANTS THAT THE OTHER PARTIES WILL RECEIVE ANY PARTICULAR AMOUNT, OR ANY, REVENUES OR PROFITS AS A RESULT OF ENTERING INTO THE BUSINESS ARRANGEMENTS DESCRIBED IN THIS AGREEMENT.

10. **Indemnification**

10.1. **By Chembio as Manufacturer**

. Chembio hereby agrees to indemnify, defend (using counsel selected by Chembio which is reasonably acceptable to Inverness) and hold harmless Inverness, its Affiliates and their respective Distributors and customers, from and against any and all liabilities, losses, (exclusive of lost profits) damages, costs and expenses (including, without limitation, reasonable attorneys' fees, court costs, and out-of pocket expenses) suffered or incurred which arise or result from: (i) the material breach of any warranty or representation of Chembio contained in this Agreement; (ii) any third party claim of personal injury (including death) or property damage arising in connection with any Licensed Product manufactured by or for Chembio; (iii) any material failure by Chembio to perform any of the covenants, agreements or obligations of Chembio contained in this Agreement; or (iv) any third party claim alleging that the manufacture, use, sale, offer for sale, import or export of the Licensed Products manufactured by or for Chembio infringes the proprietary rights of the third party claimant.

10.2. **By Sellers**

. Each seller of any Licensed Product hereunder (a "**Seller**") hereby agrees to indemnify, defend (using counsel selected by the Seller which is reasonably acceptable to the other Party) and hold harmless the other Party from and against any and all liabilities, losses (exclusive of lost profits), damages, costs, and expenses (including, without limitation, reasonable attorneys' fees, court costs, and out-of pocket expenses) suffered or incurred by the other Party which arise or result from: (i) the material breach of any warranty or any representation of the Seller contained in this Agreement; (ii) any material failure by the Seller to perform any of its covenants, agreements, or obligations contained in this Agreement; or (iii) the promotion and sale by the Seller or any Affiliate or Distributor of the Seller of any Licensed Product, except to the extent covered by the Manufacturer's defense and indemnification obligations under Section 10.1.

10.3. **Notice of Claims**

. Within thirty (30) days after a Person seeking indemnification hereunder (hereinafter the "**Indemnified Party**") has received notice of or has acquired knowledge of any claim by any Person not a Party to this Agreement of the commencement or threatened commencement of any action or proceeding by any Person not a Party to this Agreement ("**third party claim**") or has acquired knowledge of any other claim hereunder against another Party hereto ("**first party claim**") the Indemnified Party shall, if such claim is indemnifiable by the other Party pursuant hereto (hereinafter the "**Indemnifying Party**"), give the Indemnifying Party written notice of such claim and the commencement or threatened commencement of such action or proceeding, if any. Such notice shall state the nature and basis of such claim, and, if ascertainable, the amount thereof. Notwithstanding the foregoing, the failure of the Indemnified Party to give such notice shall not excuse the Indemnifying Party's obligation to indemnify and, in the case of a third party claim, defend the Indemnified Party, except to the extent the Indemnifying Party has suffered damage or prejudice by reason of the Indemnified Party's failure to give or delay in giving such notice. Within ten (10) business days of receipt of any notice issued by the Indemnified Party pursuant to this Section 10.3, the Indemnifying Party shall notify the Indemnified Party whether the Indemnifying Party acknowledges its indemnification obligation and, in the case of a third party claim, its defense obligation with respect to the claim which was the subject of the Indemnified Party's notice or whether it disclaims such obligations. In the event the Indemnifying Party disclaims or fails to timely acknowledge its obligations with respect to any claim by the Indemnified Party relating to any third party claim, the Indemnified Party shall have the right to defend such claim, with counsel of its own selection, and compromise such claim without prejudice to its right to indemnification hereunder. In the event the Indemnifying Party timely acknowledges its obligations hereunder with respect to any third party claim, the Indemnifying Party shall defend the same with counsel in accordance with this Section. Where the Indemnifying Party shall have acknowledged in writing its obligations hereunder with respect to any third party claim, the Indemnified Party may, at its expense, participate in the defense of such third party claim and no such third party claim shall be settled by the Indemnified Party without the prior written consent of the Indemnifying Party which consent shall not be unreasonably withheld or delayed. At any time after the Indemnifying Party acknowledges its obligations hereunder with respect to any third party claim, the Indemnifying Party may request the Indemnified Party to agree in writing to the payment or compromise of such third party claim (provided such payment or compromise has been previously approved in writing by the third party claimant), and, in the event the Indemnifying Party does so, the Indemnified Party shall promptly agree in writing to such settlement, unless such settlement would involve a remedy or remedies, other than the payment of money damages by the Indemnifying Party, to which the Indemnified Party reasonably objects.

10.4. **Disputes**

. In the event any party to this Agreement makes a claim against another Party under this Section 10 or in any way relating to or arising under this Agreement and further in the event the Party receiving notice of such claim fails to timely acknowledge its obligations hereunder with respect to such claim or disclaims such obligations, the relevant Parties, within forty (40) days of the date of issuance of notice by the Party making such claim, shall meet and attempt to resolve in good faith the dispute between or among the Parties with respect to such claim. If the Parties fail to resolve such dispute within seventy-five (75) days of the date of issuance of notice by the Party making such claim, the Party making such claim may thereafter commence to arbitrate the claim in accordance with the provisions set forth in Section 13.8. Upon resolution of any claim referred to in this Section 10, whether by agreement between the Parties to this Agreement or the rendering of a final arbitration award, the appropriate Party under such agreement or the Party against which the arbitration award is rendered shall, within ten (10) days of such resolution, pay over and deliver to the other Party funds in the amount of any claim as resolved.

11. **Term and Termination**.

11.1. **Term of Agreement**

. Unless otherwise terminated as expressly provided herein or with respect to any perpetual licenses granted herein, with respect to each Licensed Product, the licenses granted and appointments made hereunder shall commence on the Effective Date and continue until May 31, 2016 (the "**Term**").

11.2. **Material Breach**

. If a Party:

(a) materially breaches this Agreement in a manner which cannot be cured;

(b) materially breaches this Agreement in a manner that can be cured and a Party has failed to take steps to begin to cure within ninety (90) days following written notice of breach by the Party or Parties affected by the breach or is not diligently pursuing a cure thereafter; or

(c) is subject to a petition for relief under any bankruptcy legislation, or makes an assignment for the benefit of creditors, or is subject to the appointment of a receiver for all or a substantial part of the Party's assets, and such petition, assignment or appointment is not dismissed or vacated within ninety (90) days,

then, on each such occasion, the non-breaching Party shall have the right to exercise one or more of the following remedies: (x) upon written notice by the non-breaching Party to the breaching Party within thirty (30) days of the end of the applicable cure period (if any) (assuming that the non-breaching Party has not already given such a notice upon the occurrence of a prior material, uncured breach by the breaching Party), the non-breaching Party shall have the right to seek monetary damages for such material breach within the limitations set forth in Section 12 hereof and/or equitable relief to prevent such material breach from continuing or occurring again in the future; and, at its option, the non-breaching Party shall have the right to terminate this Agreement. Notwithstanding the foregoing, if Chembio shall be enjoined from supplying Licensed Products to Inverness because of a lawsuit regarding Intellectual Property Rights of a Third Party, or Inverness shall be enjoined from selling Licensed Products because of a lawsuit regarding Intellectual Property Rights of a Third Party, and such injunction shall in either case cause a material breach of this Agreement, the non-breaching Party shall not have the right to seek monetary damages for such material breach. Whenever a breach occurs and such breach can be cured in a timely manner, the non-breaching Party shall cooperate with the Party in breach and take reasonable steps (at the cost of the breaching Party) to allow the breaching Party to cure the breach.

11.3. **Section 365(n); Agreement to Deliver Embodiments**

. All rights and licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11, U.S. Code (the "**Bankruptcy Code**"), licenses of rights to "intellectual property" as defined in the Bankruptcy Code. The Parties agree that the licensee of such rights shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code. All rights, powers and remedies of the licensee provided under this Section 11.3 are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity in the event of any such commencement of a bankruptcy proceeding by or against the licensor.

11.4. **Effect of Termination for Breach**

. Upon any termination of this Agreement:

(a) The license grants contained in Section 2.1 and 2.2 shall terminate;

(b) subject to Sections 3.3 and 3.4, Inverness may sell any inventory of Licensed Products in its possession at the effective date of termination, but shall have no further right to Exploit the Licensed Products; and

(c) subject to the payment of royalties to Inverness pursuant to Section 3.6, Chembio may Exploit any inventory of Licensed Products in its possession as at the effective date of termination, but Chembio shall have no license rights to manufacture or Exploit any further Licensed Products.

11.5. **Survival**

. No expiration or termination of this Agreement shall affect any rights or liabilities of the Parties which may have accrued prior to the date of expiration or termination. Notwithstanding anything herein to the contrary, upon any expiration or termination of this Agreement, in addition to any provisions that by their terms survive, the provisions of Sections 3.8, 7, 8, 9.5(b), 10, 11.4, 12 and 13 shall survive and shall continue in full force and effect in accordance with their respective terms.

12. **Limitation of Liability**.

12.1. **Exclusion of Liability for Certain Damages**

. EXCEPT FOR BREACHES OF ITS CONFIDENTIALITY OBLIGATIONS HEREUNDER AND FOR VIOLATIONS OF ANOTHER PARTY'S INTELLECTUAL PROPERTY RIGHTS AND FOR DAMAGES CAUSED BY A PARTY'S GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT, IN NO EVENT SHALL A PARTY BE LIABLE TO THE OTHER PARTY FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING, WITHOUT LIMITATION, DAMAGES RESULTING FROM LOSS OF USE, PROFITS, BUSINESS OR GOODWILL, WHETHER OR NOT THE PARTY ALLEGEDLY CAUSING THE DAMAGE HAS BEEN ADVISED OF THE POSSIBILITY THEREOF. THIS SECTION 12 SHALL NOT BE CONSTRUED TO LIMIT ANY PARTY'S INDEMNIFICATION OBLIGATIONS UNDER SECTION 10 HEREOF.

12.2. **Limitation on Liability for Direct Damages**

. EXCEPT FOR BREACHES OF ITS CONFIDENTIALITY OBLIGATIONS HEREUNDER AND FOR VIOLATIONS OF ANOTHER PARTY'S INTELLECTUAL PROPERTY RIGHTS, FOR DAMAGES CAUSED BY A PARTY'S GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT, OR FOR ANY PARTY'S INDEMNIFICATION OBLIGATIONS UNDER SECTION 10 HEREOF, EACH PARTY'S MAXIMUM AGGREGATE LIABILITY TO THE OTHER PARTY, OTHER THAN FOR PAYMENTS DUE HEREUNDER, SHALL IN NO EVENT EXCEED THE AMOUNT OF $1 MILLION, WHETHER SUCH DAMAGES ARISE IN CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY OR OTHERWISE.

13. **General**.

13.1. **Waivers and Amendments**.

(a) This Agreement may be amended, modified or supplemented only by a written instrument executed by the Parties hereto.

(b) No waiver of any provision of this Agreement, or consent to any departure from the terms hereof, shall be effective unless the same shall be in writing and signed by the Party waiving or consenting thereto. No failure on the part of any Party to exercise, and no delay in exercising, any right or remedy hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such right or remedy by such Party preclude any other or further exercise thereof or the exercise of any other right or remedy. The waiver by any Party hereto of a breach of any provision of this Agreement shall not operate as a waiver of any subsequent breach. All rights and remedies hereunder are cumulative and are in addition to and not exclusive of any other rights and remedies provided by law.

13.2. **Entire Agreement**

. This Agreement, the Schedules hereto and the Related Documents constitute the entire agreement among the Parties hereto with respect to the subject matter hereof and supersede all prior agreements and understandings, whether written or oral, among the Parties, or any of the Parties, in connection with such subject matter.

13.3. **Severability**

. If any provision of this Agreement is found invalid or unenforceable by a court of competent jurisdiction, such provision shall be enforced to the maximum extent permissible by law and the other provisions of this Agreement shall remain in full force and effect.

13.4. **Relationship of the Parties**

. This Agreement shall not constitute any Party the agent or legal representative of any other Party for any purpose whatsoever, and no Party shall hold itself out as an agent of any other Party. This Agreement creates no relationship of joint venturers, partners, associates, employment or principal and agent between or among the Parties, and each of the Parties is acting as an

independent contractor. No Party is granted herein any right or authority to, and shall not attempt to, assume or create any obligation or responsibility for or on behalf of any other Party. No Party shall have any authority to bind any other Party to any contract, whether of employment or otherwise, and each Party shall bear all of their respective expenses for its operations, including, without limitation, the compensation of its employees and salespersons and the maintenance of its offices, service and warehouse facilities. Each Party shall each be solely responsible for its own employees and salespersons and for their acts and the things done by them.

13.5. **No Election of Remedies**

. The rights and remedies accorded herein are cumulative and in addition to those provided by law, and may be exercised separately, concurrently, or successively.

13.6. **Notices**

. All notices and other communications hereunder shall be in writing and shall be deemed given if delivered personally, telecopied (with confirmation) or mailed by registered or certified mail (return receipt requested) or delivered by recognized courier service providing evidence of delivery to the Parties at the following addresses:

(a) if to Chembio, to:

Chembio Diagnostic Systems, Inc.
3661 Horseblock Road
Medford, New York 11763

Attention: Lawrence A. Siebert, President
Telecopier No.: (631) 924-6033

with a copy to:

Ruskin Moscou Faltischek, P.C.
1425 Reckson Plaza
15th Floor, East Tower
Uniondale, New York 11556

Attention: Michael L. Faltischek, Esq.,
Telecopier No.: (516) 663-6640

(b) if to Inverness, to:

Inverness Medical Innovations, Inc.
51 Sawyer Road,
Waltham MA 02454
Attention: General Counsel's office
Telecopier: (781) 314 4073

or at such other address for a Party as shall be specified by like notice.

13.7. **Governing Law**

. This Agreement shall be governed by, and construed and enforced in accordance with, the substantive laws of the State of New York , without giving effect to its conflicts of laws rules.

13.8. **Dispute Resolution**

. In the event of any dispute or disagreement between or among any of the Parties as to the interpretation of any provision of this Agreement or the performance of any obligations hereunder, the matter, upon written request of any Party, shall be referred to mediation and arbitration in accordance with the procedures set forth in Schedule G to this Agreement.

13.9. **Waiver of Jury Trial**

. The Parties each hereby irrevocably and unconditionally waives all rights to trial by jury in any legal action, proceeding or counterclaim with respect to any matter whatsoever arising out of or in connection with or related to this Agreement or the enforcement thereof.

13.10. **Counterparts**

. This Agreement may be executed in two or more counterparts, all of which shall be considered one and the same agreement and shall become effective when two or more counterparts have been signed by each of the Parties and delivered to the other Parties, it being understood that all Parties need not sign the same counterpart. Facsimile execution and delivery of this Agreement

by any of the Parties shall be legal, valid and binding execution and delivery of such document for all purposes.

13.11. **Assignment**

. This Agreement is personal to each of the Parties, and no Party shall assign any of its rights or delegate any of its obligations hereunder, including without limitation by operation of law, Change of Control, or otherwise, without the prior written consent of the affected other Party or Parties, which consent shall not be unreasonably withheld or delayed, provided, however, that without the consent of the other Parties, Inverness may (i) assign its rights under this Agreement and delegate its obligations hereunder, in whole or in part, to any Person that shall acquire the business of Inverness to which this Agreement relates, or to any Affiliate of such Party, if the assignee shall assume Inverness' obligations hereunder in writing, and (ii) assign this Agreement in connection with a sale or transfer of substantially all of the assets of, or a majority interest in the voting shares of, Inverness or its corporate parent to, or the merger or consolidation of Inverness or its corporate parent with or into, any other Person. In this paragraph, "Change of Control" means any sale of the equity securities of a Party following which the equity holders of such Party immediately prior to such sale own, directly or indirectly, less than 50% of the combined voting power of the outstanding voting securities of such Party, other than in a transaction involving a sale of equity securities for the purpose of raising capital to a group of financial investors in which not less than 50% of such equity securities are purchased by a recognized venture capital or private equity fund or funds and where the management of the selling Party before the financing is substantially the same as the management of such Party after the financing..

13.12. **Force Majeure**

. No Party shall be liable for failure to perform any of its obligations under this Agreement when such failure is due to fire, flood, strikes, labor troubles or other industrial disturbances, legal restriction, riot, insurrection, or any other cause beyond the reasonable ability of the Party affected thereby to foresee and avoid, and without such party's fault or negligence ("Force Majeure"), provided that any Party claiming the existence of Force Majeure shall give notice to the other parties not more than seven (7) days after the commencement of the event of Force Majeure, and shall use prompt and diligent efforts to mitigate the effects of Force Majeure. In the event that any event of Force Majeure prevents performance for sixty (60) days or more, any other party may terminate this Agreement on written notice to all parties.

13.13. **Further Assurances**

. Each Party hereto will, upon the request of the other Party and without further consideration, execute and deliver such other instruments, and take such other actions, as such other Party may reasonably request, and at the other Party's expense, to more effectively and efficiently carry out the covenants, licenses and agreements of the Parties set forth in this Agreement and consummate the transactions contemplated by this Agreement. Without limitation of the foregoing, each exclusive licensee of rights granted hereunder shall have the right, at its sole cost and expense, to register, record and otherwise document such exclusive license in any country where there are any pending or issued Patent Rights. Such licensee may require that the other Party execute a "short form" license in order to effect the foregoing registration, recordal or other documentation in any such country, and may record such short form license, but no short form license shall in any way alter or otherwise affect the rights and obligations of the Parties hereunder.

[remainder of this page intentionally left blank]

* * *

IN WITNESS WHEREOF, the Parties have executed, or caused their duly authorized representatives to execute, this Agreement under seal as of the date first written above.

Chembio Diagnostic Systems, Inc.

By:
Title:

Inverness Medical Innovations, Inc.

By:
Title:

[Signature page to Non-Exclusive License, Marketing and Distribution Agreement]

Joint HIV Barrel Product Commercialization Agreement

PREAMBLE

This Joint HIV Barrel Product Commercialization Agreement (the "**Agreement**") is made as of September 29, 2006 ("**Effective Date**"), by and between **Chembio Diagnostic Systems, Inc.**, a Delaware corporation having its principal place of business at 3661 Horseblock Road, Medford, NY 11763 ("**Chembio**"), and **StatSure Diagnostic Systems, Inc.**, (f/k/a Saliva Diagnostic Systems) a Delaware corporation having its principal place of business at One Clarks Hill, Framingham, MA 01702 ("**SDS**") (Chembio and SDS are each referred to herein as a "Party" and jointly as the "Parties").

RECITALS

Chembio, among other things, is in the business of developing, marketing and selling products used to diagnose various diseases, including HIV, and has designed, developed or is in the process of developing products for the diagnosis or detection of HIV or HIV infection ("HIV Products") and has received approval of a pre-market application to the FDA for the HIV Barrel Product for manufacture by Chembio at its facility in Medford, New York and for Chembio to market to clinical laboratories and hospitals in the United States

SDS, among other activities, is in the business of developing, manufacturing and marketing medical diagnostic products and owns the SDS Patents.

SDS, Chembio and Inverness Medical Innovations, Inc., a Delaware corporation, ("Inverness") have entered into a License, Marketing and Distribution Agreement of even date herewith (the "3-Way Agreement"), pursuant to which Inverness has been granted the worldwide exclusive right to market and distribute the HIV Barrel Product.

During the Term, to the extent such license is necessary, SDS wishes to license the SDS Patents to Chembio on an exclusive basis with respect to the HIV Barrel Product, and Chembio wishes to accept such license without acknowledging or agreeing to its necessity with respect to the HIV Barrel Product, on an exclusive basis, with respect to manufacture of the HIV Barrel Products solely for resale by Inverness as long as the 3-Way Agreement is in effect or, in the event of termination of the 3-Way Agreement, as otherwise set forth herein.

The Parties may also enter into such other ancillary agreements, licenses and covenants as may be appropriate to permit the parties to fulfill the business objectives of this Agreement.

Chembio and SDS wish to collaborate exclusively with each other, and to agree to work only with each other and not alone, to develop and commercialize products in the Barrel Field for the diagnosis or detection of HIV or HIV infection in order to facilitate introduction, distribution and sale of such products in the market.

NOW, THEREFORE, in consideration of the premises and the mutual promises, covenants and conditions hereinafter set forth, the receipt and adequacy of which are hereby acknowledged, Chembio and SDS hereby agree as follows:

1. **Definitions**.

1.1. **Certain Definitions.** For purposes of this Agreement, in addition to the terms that are defined on first use herein, the following terms shall have the following meanings:

(a) The "**Act**" shall mean the Federal Food, Drug and Cosmetic Act, as amended, and all relevant federal regulations pertaining thereto.

(b) "**Affiliate**" shall mean any Person that controls, is controlled by, or is under common control with a Party hereto. For purposes of this definition, "control" shall mean (i) in the case of corporate entities, direct or indirect ownership of a majority of the stock or shares having the right to vote for the election of directors, and (ii) in the case of non-corporate entities, direct or indirect ownership of a majority of the equity interest with the power to direct the management and policies of such non-corporate entities.

(c) **"Audit"** shall mean examination of each and every document relating to the licenses and rights granted herein, including but not limited to books, records, agreements, communications, shipping records, purchase orders, invoices, credit memos and record of payments received or made by a nationally recognized public accounting firm.

(d) "**Barrel Field**" means diagnostic testing for the presence of HIV antibodies utilizing an integrated in-vitro diagnostic testing device that (i) is a single-use disposable device, (ii) collects a physiologic sample from a patient directly into the device using a tip at one end of the device and delivers that sample into a system contained in the device, where the reaction reagent medium (for example, a reagent strip) is enclosed in a barrel or other container with a transparent portion which allows the results of the reaction to be visible, designed to protect the user from contact with its contents, (iii) produces a visually readable result in less than twenty minutes, and (iv) is primarily designed to be used in a Point of Care environment or for self-testing by consumers**.**

(e) "**Challenge**" means, with respect to Patent Rights, to challenge the validity or enforceability of any Patent Rights, including without limitation by (i) filing a declaratory judgment action in which Patent Rights are alleged to be invalid or unenforceable; (ii) citing prior art pursuant to 35 U.S.C. Sec. 301, making a request for re-examination of Patent Rights pursuant to 35 U.S.C. Sec. 302 and/or 311, or provoking or becoming party to an interference with an application for Patent Rights pursuant to 35 U.S.C. Sec. 135; or (iii) filing or commencing any opposition, cancellation, nullity or similar proceedings against Patent Rights in any country.

(f) "**Chembio IP**" shall mean all proprietary rights and Intellectual Property Rights, including but not limited to Patent Rights, owned or Controlled by Chembio, which are necessary or useful for, or would be infringed or that Chembio asserts would be infringed, by the manufacture, use, sale, distribution, import or export of the HIV Barrel Products or New HIV Barrel Products, whether in existence now or in the future, including but not limited to those listed on Schedule A.

(g) "**Confidential Information**" shall mean all Technology and ideas and information of any kind, whether in written, oral, graphical, machine-readable or other form, whether or not marked or identified as confidential or proprietary, which are transferred, disclosed or made available by either Party hereto to the other.

(h) **"Control"** or **"Controlled by"** shall mean, in the context of Patent Rights or other Intellectual Property Rights, possession of the ability on the part of a Party to grant access to or a license or sublicense as provided for herein without violating the terms of any agreement or other arrangement with any Third Party existing at the time such Party would be required hereunder to grant another Party such access or license or sublicense.

(i) "**Distributor**" shall mean any Third Party to which a Party grants a right to resell or distribute HIV Barrel Products or New HIV Barrel Products.

(j) "**Exploit**" or "**Exploitation**" shall mean to sell, offer for sale, import, export, transport, register, distribute, promote and market, together with other activities typically associated with maximizing the market penetration, profit margins and commercialization of a diagnostic medical product that is marketed to hospitals and clinical laboratories for professional use and to doctors' offices, insurance companies, military facilities, and other Point of Care clinics, as well as to the public for self-testing.

(k) "**FDA**" means the U.S. Food and Drug Administration.

(l) "**First Commercial Sale**" shall mean, with respect to a product, the first sale to any Third Party.

(m) "**GAAP**" means United States Generally Accepted Accounting Principles, as applicable to the Party in question.

(n) "**GMP**" means current Good Manufacturing Practices as promulgated by the FDA.

(o) "**HIV Barrel Product**" means the product for HIV testing known as SURE CHECK(R) HIV 1/2 as described in Chembio's PMA on file with the FDA and further described in the SURE CHECK(R) HIV 1/2 package insert, Catalog #HIV202, attached hereto as Schedule A, together with any improvements thereto.

(p) "**Intellectual Property Rights**" shall mean (i) Patent Rights; (ii) rights associated with works of authorship including copyrights, copyright applications and copyright registrations; and (iii) rights relating to the protection of trade secrets, know-how and Confidential Information, but shall not include any rights to trade marks, trade names, or other distinctive brand names or logos.

(q) "**New HIV Barrel Product**" means (i) the patent pending product in the Barrel Field for the diagnosis or detection of HIV or HIV infection currently being designed and developed by Chembio which Chembio describes as set forth in Schedule D, and/or (ii) any other new product in the Barrel Field for the diagnosis or detection of HIV or HIV infection Controlled by SDS or Chembio.

(r) "**Patent Rights**" shall mean all patents, patent applications and inventions on which patent applications are filed and all patents issuing therefrom worldwide, all disclosures of inventions, together with any extensions, registrations, confirmations, reissues, divisionals, continuations, continuations-in-part, reexamination certificates, substitutions or renewals, supplemental protection certificates, term extensions (under applicable patent law or other law), provisional rights and certificates of inventions.

(s) "**Person**" shall mean an individual, corporation, partnership, limited partnership, limited liability company, unincorporated association, trust, joint venture or other organization or entity, including a governmental authority.

(t) "**POC**" or "**Point of Care**" means an environment where sampling and testing is performed in the presence or near-presence of the patient.

(u) "**Related Documents**" shall mean the 3-Way Agreement, the Settlement Agreement between SDS and Chembio, the License and Distribution Agreement between SDS and Inverness, the License and Distribution Agreement between Chembio and Inverness, and the HIV Cassette Agreement between Chembio and Inverness.

(v) "**SDS Patents**" shall mean all Patent Rights owned or Controlled by SDS that would be infringed, or that SDS asserts would be infringed, by the manufacture, use, sale, distribution, import or export of the HIV Barrel Products or New HIV Barrel Products, whether in existence now or in the future, including but not limited to those listed in Schedule B.

(w) **"Sell"** shall mean to sell, offer for sale, market, promote, transport, export and use in furtherance of sales activities.

(x) "**Settlement Agreement**" shall mean the Settlement Agreement of even date herewith between the Parties.

(y) "**Sublicensee**" shall mean any sublicensee of any of the rights granted to a Party under this Agreement, other than an Affiliate or a Distributor.

(z) "**Technology**" shall mean all techniques, inventions, practices, procedures, knowledge, improvements, designs, processes, protocols, compositions, products, methods, works of authorship, know-how, data, clinical data, preclinical data, research and creations (whether or not subject to protection by any Intellectual Property Rights).

(aa) "**Third Party**" shall mean any Person other than SDS or Chembio or an Affiliate of either of them.

(bb) "**United States**" means the United States of America and its territories and possessions, including without limitation Puerto Rico and the U.S. Virgin Islands.

1.2. **Additional Definitions**. Certain additional capitalized terms are defined in the Preamble or the Recitals or below in the body of this Agreement and, if not otherwise defined, shall have the meaning as set forth in the 3-Way Agreement.

2. **Joint Exploitation of HIV Products in the Barrel Field.**

2.1 **In General**. The Parties shall act together in all matters relating to the Exploitation of the HIV Barrel Product and any New HIV Barrel Product, with a goal of maximizing the commercial value of the HIV Barrel Product and any New HIV Barrel Product, both in geographic markets and in customer market segments.

2.2 **Under the 3-Way Agreement**. The Parties shall act together in all matters under the 3-Way Agreement, other than Chembio's right and obligation to manufacture and supply the HIV Barrel Product thereunder. Without limiting the generality of the foregoing:

(a) Neither Party shall (i) give any notice to Inverness under the 3-Way Agreement, (ii) terminate or attempt to terminate the 3-Way Agreement, or (iii) modify or amend the 3-Way Agreement without the prior written consent of the other Party. For clarity, if the Parties do not both agree to take an action described in the preceding sentence, then such action shall not be taken.

(b) In order to keep SDS properly informed, Chembio shall forward all forecasts, Purchase Orders or alterations thereof received from Inverness pursuant to Section 7.2 or 7.3 of the 3-Way Agreement to SDS within five (5) business days of receipt thereof by Chembio.

(c) In the event either Party makes sales of HIV Barrel Products to a Third Party (other than Inverness) as permitted by the 3-Way Agreement, the selling Party shall pay the other Party a royalty of five percent (5%) of the Net Sales (as defined in the 3-Way Agreement) thereof. Sections 5.6 (other than subsections (a) and (d)) and Section 5.7 (other than subsections (b), (c), and (e)) shall apply to such royalties with appropriate adjustments to reflect the differences in Payer and Payee.

2.3 **Outside the 3-Way Agreement**. In the event of any termination or expiration of the 3-Way Agreement, SDS and Chembio agree that they will jointly seek a qualified Third Party to replace Inverness as the Distributor of the HIV Barrel Product and any New HIV Barrel Product and will enter into a written agreement with respect thereto. SDS and Chembio further agree that neither Party will Exploit the HIV Barrel Product or any New HIV Barrel Product except pursuant to this Agreement or another written agreement with the other Party, and neither Party will enter into a license agreement, a distribution agreement, a joint venture, or any other agreement with a Third Party involving the Exploitation of a product in the Barrel Field for the diagnosis or detection of HIV or HIV infection without the prior written agreement of the other Party. If any royalties are due to Inverness pursuant to Section 5.6 of the 3-Way Agreement as a result of any Exploitation pursuant to this Section 2.3, then the sharing of such royalties will be determined in accordance with the agreement for such Exploitation executed pursuant to this Section 2.3.

2.4 **Non-Competition**. Neither Party shall manufacture, promote, market, distribute, sell, offer for sale, import, export, seek or obtain regulatory approval of the HIV Barrel Product or any New HIV Barrel Product except under this Agreement and neither Party shall grant any license to, or in any way assist, any Affiliate or Third Party to do so. Each Party acknowledges and agrees that the exclusivity resulting from this Section is of critical importance to the other Party, and that without such exclusivity, the other Party would not have entered into this Agreement.

2.5 **Joint Operating Committee.**

(a) **The JOC.** Promptly after the execution of the 3-Way Agreement, the Parties shall establish a Joint Operating Committee ("**Joint Operating Committee**" or "**JOC**"), which shall be responsible for planning and coordinating activities under this Joint Exploitation Agreement. The JOC shall be composed of three (3) members, one

designated by each Party and one agreed upon by the two Parties, who (in the case of the third member) shall have no affiliation or relationship with either Party. Either Party may replace its representative at any time upon prior written notice to the other Party. If a Party's representative is unable to attend a meeting, such Party may designate an alternate to attend such meeting and perform the functions of such representative.

(b) **Responsibilities of JOC.** The Joint Operating Committee shall have the authority to make all decisions under Article 2 and Article 5 of this Agreement, including without limitation all actions under the 3-Way Agreement or outside the 3-way Agreement in the event of termination or expiration of the 3-way Agreement, as set forth in Sections 2.2 and 2.3. Neither Party shall take any action under the 3-Way Agreement or any action to Exploit the HIV Barrel Product or any New HIV Barrel Product except pursuant to a specific decision of the JOC.

(c) **Decision Making Authority.** With respect to the responsibilities of the Joint Operating Committee, each member (or alternate designated by a Party if a member representing a Party is unable to attend) shall have one (1) vote in all decisions. All decisions shall be made by majority vote and be memorialized.

(d) **Meetings; Minutes.** The Joint Operating Committee shall meet quarterly, or more often as otherwise agreed by the Parties, at such locations as the Parties agree. The JOC may meet in person, by teleconference, videoconference or as otherwise agreed. Minutes of the JOC meetings shall be taken, and shall, at a minimum, record all decisions made. A draft of such minutes shall be promptly provided to and approved by both Parties in accordance with a formal approval process established by the JOC. A Party may, with the prior consent of the other Party, invite a reasonable number of non-voting employees, consultants or scientific advisors to attend the meetings of the JOC, provided that such invitees are bound by appropriate confidentiality obligations. Decisions shall be effective upon execution of a consent or approval agreed by a majority of the Joint Operating Committee.

(e) **Other Communications.** In addition to formal meetings, the Joint Operating Committee representatives shall communicate as necessary to ensure the appropriate joint Exploitation of the HIV Barrel Product and any New HIV Barrel Product. Each Party shall have reasonable access to the other Party's facilities and personnel to facilitate joint Exploitation of the HIV Barrel Product and any New HIV Barrel Product, upon reasonable notice.

(f) **Initial Members.** The Initial Members of the Joint Operating Committee shall be Lawrence A. Siebert, Steve M. Peltzman and a third person to be agreed upon by SDS and Chembio.

(g) **Public Announcements.** Except as authorized in this Agreement or otherwise required by applicable law, regulation or the rules of any securities exchange or other trading market on which such Party's securities are listed, all public communications relating to the actions of the Joint Operating Committee shall be subject to the approval of the Parties.

3. **Licenses and Intellectual Property Matters.**

3.1 **Exclusive Right to Manufacture**. SDS, on and subject to the terms and conditions contained herein and in the 3-Way Agreement, hereby grants to Chembio, and Chembio hereby accepts from SDS, without acknowledging or agreeing to its necessity with respect to the HIV Barrel Product, a worldwide exclusive license to manufacture the HIV Barrel Products for resale by Inverness under the 3-Way Agreement or, in the event of termination of the 3-Way Agreement, as otherwise set forth herein.

3.2 **Technology.** Subject to Article 4, the Parties will give each other access to their respective know-how and Technology relevant to the HIV Barrel Product and any New HIV Barrel Products in order to optimize manufacturing processes and quality and reduce manufacturing costs. Notwithstanding the foregoing, neither Party has any obligation to disclose its intellectual property, including the Chembio IP, except as may be required to purchase, supply and assemble hardware components related to the HIV Barrel Product and any New HIV Barrel Product.

3.3 **Patent Validity.** Chembio, having investigated and analyzed the SDS Patents, hereby acknowledges that each of the SDS Patents is valid and enforceable.

3.4 **No Validity Challenge.** In order to assure the orderly Exploitation of the HIV Barrel Product and New HIV Barrel Products and to make such products available to the public to address medical needs:

(a) Chembio agrees not to (and to cause its Affiliates not to) Challenge Patent Rights in the SDS Patents, or to assist any Third Party in doing so.

(b) SDS agrees not to (and to cause its Affiliates not to) Challenge any Patent Rights included in the Chembio IP or to assist any party in doing so, unless such Patent Rights are enforced or threatened to be enforced against SDS or an SDS customer or partner for infringement resulting from an SDS product or service other than a product in the Barrel Field that diagnoses or detects HIV or HIV infection which SDS product or service is sold in violation of this Agreement or the 3-Way Agreement. SDS further agrees not to challenge Chembio's right to continued use for manufacture of the HIV Barrel Product of the Confidential Information or Technology utilized by Chembio in the manufacture of the HIV Barrel Product.

(c) Neither Party has investigated the Confidential Information or Technology utilized by the other party in connection with the manufacture of the HIV Barrel Product, and nothing contained herein shall be construed as an admission by either Party that such Confidential Information or Technology is or is not covered by the SDS Patents or the Chembio IP.

3.5 **Consequences of Violation**. If either Party Challenges the Patent Rights of the other Party in violation of Section 3.4, then the Party whose rights were the subject of the Challenge (the "Challenged Party"), may, by written notice to the Party violating Section 3.4 (the "Challenging Party"):

(i) terminate this Agreement or terminate any or all rights and licenses granted to the Challenging Party hereunder, and

(ii) if the 3-Way Agreement is in effect at the time of the violation of Section 3.4, then if the Challenging Party is Chembio, reduce Chembio's share of the SDS/Chembio share of Net Sales for the HIV Barrel Product or any New HIV Barrel Product under the 3-Way Agreement to 20% from 50% permanently; and if the Challenging Party is SDS, reduce SDS's share of the SDS/Chembio share of Net Sales for the HIV Barrel Product or any New HIV Barrel Product under the 3-Way Agreement to 20% from 50% permanently. The Challenged Party shall have the right to notify Inverness of any action taken under this Section, and the Parties agree that Inverness shall have no liability for any action taken to distribute the SDS/Chembio share of Net Sales in accordance with such notice. In the event the alleged Challenging Party disputes in good faith that it has Challenged the Patent Rights of the other Party, then the matter will be resolved in accordance with Section 10.8 and the amounts of the foregoing reductions will be placed in escrow until the matter is resolved.

4. **Confidentiality**.

4.1 **Limited Disclosure and Use**. Each of Chembio and SDS shall hold in confidence any Confidential Information disclosed by the other Party or otherwise obtained by such Party from the other Party as a result of this Agreement or the Settlement Agreement, and each of SDS and Chembio shall protect the confidentiality thereof with the same degree of care that it exercises with respect to its own information of a like nature, but in no event less than reasonable care. Without the prior written consent of the disclosing Party, a receiving Party shall not use, disclose, or distribute any Confidential Information, in whole or in part, except as required to perform such Party's obligations or exercise such Party's rights hereunder or under the Settlement Agreement. Access to the disclosing Party's Confidential Information shall be restricted to the receiving Party's employees and agents, who, in each case, need to have access to carry out a permitted use and are bound in writing to maintain the confidentiality of such Confidential Information.

4.2 **Exceptions.** The obligations set forth in Section 4.1 shall not apply to any portion of the Confidential Information that the receiving Party can demonstrate by legally sufficient evidence: (i) now or hereafter, through no act or failure to act on the part of the receiving Party, is or becomes generally available; (ii) is known to the receiving Party at the time of receiving such Confidential Information and not subject to an obligation of confidentiality to a Third Party; (iii) is hereafter furnished to the receiving Party by a Third Party as a matter of right (and without violating any agreement with the disclosing Party) without restriction on use or disclosure; or (iv) is independently developed by the receiving Party without use of any Confidential Information received from the other Party. In addition, each receiving Party may disclose Confidential Information to the extent such disclosure is reasonably necessary to prosecute or defend litigation, to comply with applicable law or regulation or the rules of any securities exchange or other trading market on which such party's securities are listed, to protect

Intellectual Property Rights, to obtain necessary or desirable regulatory approvals, to respond to a valid order of a court or other governmental body or any political subdivision thereof, or to conduct preclinical or clinical trials, provided that, other than with respect to disclosure for protecting Intellectual Property Rights, the receiving Party shall use reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed.

4.3 **Use of Name; Disclosure of Terms of the Agreement.** Except as authorized in this Agreement or otherwise required by applicable law, regulation or the rules of any securities exchange or other trading market on which such Party's securities are listed, neither Party shall use the name of the other Party in any publicity or advertising without the prior written approval of the other Party, except that either Party may disclose that it has entered into this Agreement and the Settlement Agreement. Except as may be required by applicable law, regulation or the rules of any securities exchange or other trading market on which such Party's securities are listed, neither Party shall disclose any terms or conditions of this Agreement or the Settlement Agreement without the prior written consent of the other Party, provided that a Party may disclose such terms and conditions to any Third Party with whom such Party has entered into or proposes to enter into a business relationship (including any transaction that would result in a permitted assignment in accordance with the terms and conditions of Section 9.11 hereof), provided any such Third Party is informed of the confidentiality restrictions herein with respect to such terms and conditions and agrees to abide by such restrictions.

4.4 **Survival.** The obligations set forth in this Article 4 shall survive any termination or expiration of this Agreement in perpetuity (with respect to trade secrets) and for a period of five (5) years (with respect to all other data and information).

5. **Manufacturing**

5.1 **SDS Manufacturing Equipment**. SDS will lease a one-head assembler to Chembio. Chembio will make lease payments to SDS in accordance with Schedule C.

5.2 **Reduction of Manufacturing Costs**. Chembio will use commercially reasonable efforts to reduce Cost (as defined in the 3-Way Agreement) of the HIV Barrel Product for supply to Inverness under the 3-Way Agreement, taking into consideration regulatory and quality obligations. The Parties will review all operations involved in such manufacturing and consult on appropriate changes in the process. Without limiting the generality of the foregoing, the Parties will consider (through the JOC) use of a Third Party manufacturer if significant cost savings can be achieved, as long as such Third Party manufacture is in compliance with applicable regulations, will not impair quality obligations or cause a material change in registrations or product approvals.

5.3 **Manufacturing Failures Under the 3-Way Agreement**. In the event Chembio does not supply the quantity and/or quality of HIV Barrel Products required under the 3-Way Agreement, then the Joint Operating Committee, with the assistance of the Parties, will develop appropriate reasonable business strategies to fulfill such requirements.

6. **Joint Patent Rights.**

The Parties do not intend to engage in joint research activities and acknowledge that they have no obligation to do so. Nonetheless, in the course of activities hereunder, patentable inventions may be made. As between the Parties, ownership of Patent Rights shall be determined in accordance with inventorship. The determination of inventorship for Patent Rights shall be made in accordance with applicable laws relating to inventorship set forth in the patent laws of the United States. As between the Parties, SDS shall own any invention that is conceived or reduced to practice by an employee of SDS solely (or jointly with a Third Party subcontractor of SDS), and Chembio shall own any Invention that is made solely by an employee of Chembio (or jointly with a Third Party subcontractor of Chembio). Any invention that is made jointly by both an employee of SDS (or a Third Party subcontractor of SDS) and an employee of Chembio (or a Third Party of Chembio) shall be jointly owned by the Parties ("**Joint Patent Rights**"). Each Party retains an undivided one-half interest in and to the Joint Patent Rights. Joint Patent Rights shall only be utilized in the Barrel Field under this Agreement. The Parties shall jointly control the filing and prosecution of patent applications for Joint Patent Rights, using mutually agreed counsel. Each Party may independently exercise its ownership rights in and to such Joint Patent Rights, for any other field, and including the right to license and sublicense or otherwise to exploit, transfer or encumber its ownership interest, without an accounting or obligation to, or consent required from, the other Party.

7. **Representations and Warranties.**

7.1 **Corporate Power.** Each Party represents to the other Party that it has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof. Each Party represents to the other that this Agreement constitutes a valid and binding agreement, enforceable against it in accordance with its terms.

7.2 **No Default or Violation.** Each Party represents and warrants to the other Party that the execution, delivery and performance of this Agreement does not (i) violate or require any registration, qualification, consent, approval, or filing under, (1) any law, statute, ordinance, rule or regulation applicable to it, or (2) any judgment, injunction, order, writ or decree of any court, arbitrator, or governmental entity by which such Party or any of its assets or properties may be bound or (ii) conflict with, require any consent, approval, or filing under, result in the breach or termination of any provision of, constitute a default under, result in the acceleration of the performance of any obligations under, result in the vesting or enhancement of any other Person's rights under, or result in the creation of any lien upon any of such Party's properties, assets, or businesses pursuant to (x) its organizing documents or By-Laws or (y) any material indenture, mortgage, deed of trust, license, permit, approval, consent, franchise, lease, contract, or other instrument or agreement to which such Party is a party or by which such Party or any of such Party's properties or assets is bound.

7.3 **Exclusion of Other Representations and Warranties.** EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY REPRESENTATIONS OR WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT. NEITHER PARTY WARRANTS THAT THE OTHER PARTY WILL RECEIVE ANY PARTICULAR AMOUNT, OR ANY, REVENUES OR PROFITS AS A RESULT OF ENTERING INTO THE BUSINESS ARRANGEMENTS DESCRIBED IN THIS AGREEMENT.

8. **Term and Termination**.

8.1 **Term of Agreement.** Unless otherwise terminated by agreement of the Parties, this Agreement shall continue in effect perpetually with respect to all products in the Barrel Field for the diagnosis or detection of HIV or HIV infection.

8.2 **Material Breach.** If there is a:

(i) material breach by a Party of this Agreement which cannot be cured; or

(ii) material breach by a Party of this Agreement that can be cured and such Party has failed to take steps to begin to cure the breach within sixty (60) days following written notice specifying the material breach by the Party affected by the breach or is not diligently pursuing a cure thereafter, or

(iii) is subject to a petition for relief under any bankruptcy legislation, or makes an assignment for the benefit of creditors, or is subject to the appointment of a receiver for all or substantially part of the Party's assets, and such petition, assignment or appointment, if involuntary, is not dismissed or vacated within ninety (90) days.

then, an Event of Default shall be deemed to have occurred. Upon an Event of Default, the non-breaching Party shall have the right to exercise one or more of the following remedies upon written notice by the non-breaching Party to the breaching Party within thirty (30) days of an Event of Default (if any) (assuming that the non-breaching Party has not already given such a notice upon the occurrence of a prior material, uncured breach by the breaching Party): (i) to seek monetary damages for such material breach within the limitations set forth in Section 9 hereof; (ii) to seek equitable relief to prevent such material breach from continuing or occurring again in the future; (iii) if the Event of Default can be cured, to effect a cure and be reimbursed for the costs incurred or (iv) at its option, to terminate this Agreement upon written notice to the breaching Party; provided, however, that in the event the alleged breaching Party in good faith challenges the allegation of breach, then the matter shall be resolved in accordance with Section 10.8, and the cure period set forth in Section 8.2(ii), which shall be reduced to thirty (30) days, shall only commence upon a decision pursuant to Section 10.8 that such breach has occurred.

8.3 **Survival**. No expiration or termination of this Agreement shall affect any rights or liabilities of the Parties which may have accrued prior to the date of expiration or termination. Notwithstanding anything herein to the contrary, upon any expiration or termination of this Agreement, in addition to any provisions that by their terms survive, the provisions of Sections [**to be updated**] shall survive and shall continue in full force and effect in accordance with their respective terms.

9**. Limitation of Liability.**

9.1 EXCEPT FOR BREACHES OF ITS CONFIDENTIALITY OBLIGATIONS HEREUNDER AND FOR VIOLATIONS OF THE OTHER PARTY'S INTELLECTUAL PROPERTY RIGHTS AND FOR DAMAGES CAUSED BY A PARTY'S GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT, IN NO EVENT SHALL A PARTY BE LIABLE TO ANY OTHER PARTY FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING, WITHOUT LIMITATION, DAMAGES RESULTING FROM LOSS OF USE, PROFITS, BUSINESS OR GOODWILL, WHETHER OR NOT THE PARTY ALLEGEDLY CAUSING THE DAMAGE HAS BEEN ADVISED OF THE POSSIBILITY THEREOF.

10**. General**.

10.1 **Waivers and Amendments**.

(a) This Agreement may be amended, modified or supplemented only by a written instrument executed by the Parties hereto. For clarity, the Joint Operating Committee shall have no power to amend or modify this Agreement.

(b) No waiver of any provision of this Agreement, or consent to any departure from the terms hereof, shall be effective unless the same shall be in writing and signed by the Party waiving or consenting thereto. No failure on the part of either Party to exercise, and no delay in exercising, any right or remedy hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such right or remedy by such Party preclude any other or further exercise thereof or the exercise of any other right or remedy. The waiver by either Party hereto of a breach of any provision of this Agreement shall not operate as a waiver of any subsequent breach. All rights and remedies hereunder are cumulative and are in addition to and not exclusive of any other rights and remedies provided by law.

10.2 **Entire Agreement**. This Agreement, the Schedules hereto and the Related Documents constitute the entire agreement between the Parties hereto with respect to the subject matter hereof and supersede all prior agreements and understandings, whether written or oral, between the Parties in connection with such subject matter.

10.3 **Severability**. If any provision of this Agreement is found invalid or unenforceable by a court of competent jurisdiction, such provision shall be enforced to the maximum extent permissible by law and the other provisions of this Agreement shall remain in full force and effect.

10.4 **Relationship of the Parties**. This Agreement shall not constitute either Party the agent or legal representative of the other Party for any purpose whatsoever, and neither Party shall hold itself out as an agent of the other Party. This Agreement creates no relationship of joint venturers, partners, associates, employment or principal and agent between the Parties and each of the Parties is acting as an independent contractor. Neither Party is granted herein any right or authority to, and shall not attempt to, assume or create any obligation or responsibility for or on behalf of the other Party. Neither Party shall have any authority to bind the other Party to any contract, whether of employment or otherwise, and each Party shall bear all of its respective expenses for its operations, including, without limitation, the compensation of its employees and salespersons and the maintenance of its offices, service and warehouse facilities. Each Party shall each be solely responsible for its own employees and salespersons and for their acts and the things done by them.

10.5 **No Election of Remedies**. The rights and remedies accorded herein are cumulative and in addition to those provided by law, and may be exercised separately, concurrently, or successively.

10.6 **Notices**. All notices and other communications hereunder shall be in writing and shall be deemed given if delivered personally, telecopied (with confirmation) or mailed by registered or certified mail (return receipt requested) or delivered by recognized courier service providing evidence of delivery to the Parties at the following addresses:

If to Chembio, to:

Chembio Diagnostic Systems, Inc.
3661 Horseblock Road
Medford, New York 11763
Attention: Lawrence A. Siebert, President
Telecopier No.: (631) 924-6033

with a copy to:

Ruskin Moscou Faltischek, P.C.
1425 Reckson Plaza
15th Floor, East Tower
Uniondale, New York 11556
Attention: Michael L. Faltischek, Esq,
Telecopier No.: (516) 663-6640

If to SDS, to:

StatSure Diagnostic Systems, Inc.
One Clark's Hill
Framingham, MA 01702
Attention: Chief Executive Officer
Telecopier No.:

with a copy to:

Mintz, Levin, Cohn, Ferris,
Glovsky and Popeo, P.C.
One Financial Center
Boston, MA 02111
Attention: Jeffrey M. Wiesen, Esq.
Telecopier No.: 617-542-2241

or at such other address for a Party as shall be specified by like notice.

10.7 **Governing Law**. This Agreement shall be governed by, and construed and enforced in accordance with, the substantive laws of the State of New York , without giving effect to its conflicts of laws rules.

10.8 **Dispute Resolution.** In the event of any dispute or disagreement between the Parties as to the interpretation of any provision of this Agreement or the performance of any obligations hereunder, the matter, upon written request of either Party, shall be referred to **[mediation and]** arbitration in accordance with the procedures set forth in Schedule F to this Agreement.

10.9 **Waiver of Jury Trial**. The Parties each hereby irrevocably and unconditionally waives all rights to trial by jury in any legal action, proceeding or counterclaim with respect to any matter whatsoever arising out of or in connection with or related to this Agreement or the enforcement thereof.

10.10 **Counterparts**. This Agreement may be executed in two or more counterparts, all of which shall be considered one and the same agreement and shall become effective when two or more counterparts have been signed by both of the Parties and delivered to the other Party, it being understood that both Parties need not sign the same counterpart. Facsimile execution and delivery of this Agreement by either Party shall be legal, valid and binding execution and delivery of such document for all purposes.

10.11 **Assignment**. This Agreement is personal to each of the Parties, and neither Party shall assign any of its rights or delegate any of its obligations hereunder without the prior written consent of the other Party, which consent may be withheld for any reason, provided, however, that without the consent of the other Party, each Party may (i) assign its rights under this Agreement and delegate its obligations hereunder, in whole or in part, to any Person that shall acquire the business of such Party to which this Agreement relates, or to any Affiliate of such Party, if the assignee shall assume such Party's obligations hereunder in writing, and (ii) assign this Agreement in connection with a sale or transfer of substantially all of the assets of, or a majority interest in the voting shares of, such Party or its corporate parent to, or the merger or consolidation of such Party or its corporate parent with or into, any other Person.

10.12 **Force Majeure**. Neither Party shall be liable for failure to perform any of its obligations under this Agreement when such failure is due to fire, flood, strikes, labor troubles or other industrial disturbances, legal restriction, riot, insurrection, or any other cause beyond the reasonable control of the Party affected thereby.

[remainder of this page intentionally left blank]

---

* * *

IN WITNESS WHEREOF, the Parties have executed, or caused their duly authorized representatives to execute, this Agreement under seal as of the date first written above.

Chembio Diagnostic Systems, Inc.

By:

Title:

StatSure Diagnostic Systems, Inc.

By:

Title:

FINAL

Settlement Agreement

PREAMBLE

This Settlement Agreement (the "**Agreement**") is made as of September 29, 2006 ("**Effective Date**"), by and between **Chembio Diagnostic Systems, Inc.**, a Delaware corporation having its principal place of business at 3661 Horseblock road, Medford, NY 11763 ("**Chembio**"), and **StatSure Diagnostic Systems, Inc.**, (f/k/a Saliva Diagnostic Systems) a Delaware corporation having its principal place of business at One Clarks Hill, Framingham, MA 01702 ("**SDS**") (Chembio and SDS are each referred to herein as a "Party" and jointly as the "Parties").

RECITALS

Chembio has brought an action against SDS (Civil Action No. 04-CV-1149) in the United States District Court for the Eastern District of New York seeking a declaration of invalidity of the SDS Patents, a declaration of unenforceability of the SDS Patents and a declaration of non-infringement of the SDS Patents by the HIV Barrel Product (the "Pending Litigation"). SDS has filed an Answer and Counterclaim alleging that the HIV Barrel Product infringes the SDS Patent Number 5,935,854 and has sought leave to amend its pleading to assert that Chembio has breached the Manufacturing Agreement between SDS and Chembio dated January __, 2001, (the "SDS/Chembio Manufacturing Agreement"), among other things (the "Counterclaim").

SDS and Chembio with to dismiss with prejudice the Pending Litigation and the Counterclaim as set forth herein.

SDS, Chembio and Inverness Medical Innovations, Inc., a Delaware corporation, ("Inverness") have entered into a License, Marketing and Distribution Agreement of even date herewith (the "3-Way Agreement").

SDS and Chembio intend to provide for joint Exploitation of products in the Barrel Field for the diagnosis or detection of HIV infection pursuant to the 3-Way Agreement and upon its expiration or termination through a separate agreement between them ("Joint HIV Barrel Product Commercialization Agreement").

NOW, THEREFORE, in consideration of the premises and the mutual promises, covenants and conditions hereinafter set forth, the receipt and adequacy of which are hereby acknowledged, Chembio and SDS hereby agree as follows:

1. **Definitions**.

For purposes of this Agreement, in addition to the terms that are defined on first use herein, capitalized terms herein shall have the meanings defined in the 3-Way Agreement unless otherwise defined herein except that the 3-Way Agreement shall be a Related Document for purposes of this Agreement; provided, however, that no amendment of any definition in the 3-Way Agreement will amend any definition in this Agreement unless the Parties expressly agree in writing.

2. **Settlement of Pending Litigation**

2.1. **Dismissal of Pending Litigation.** Chembio and SDS will execute and file, within five business days of the effective date of this Agreement, a stipulation of dismissal in the form of Exhibit A hereto, dismissing the Pending Litigation. Nothing in this Agreement or in any of the Related Documents shall preclude any party from asserting res judicata, collateral estoppel, or law of the case with respect to any ruling(s) previously made in the Pending Litigation. Nothing herein shall grant any rights under any SDS Patents to Chembio for any products other than HIV Barrel Products.

2.2. **SDS Agreement Not to Sue.** SDS agrees not to bring (and shall cause its Affiliates not to bring) an infringement action under the SDS Patents against Chembio with respect to any product in the Barrel Field for the diagnosis or detection of HIV infection that is being jointly marketed and sold by SDS and Chembio under the 3-Way Agreement or the Joint HIV Barrel Product Commercialization Agreement.

2.3. **Chembio Agreement Not to Sue**. Chembio agrees not to bring (and shall cause its Affiliates not to bring) an action against SDS alleging that any product in the Barrel Field for the diagnosis or detection of HIV infection that is being jointly marketed and sold by SDS and Chembio under the 3-Way Agreement or the Joint HIV Barrel Product Commercialization Agreement does not infringe any of the SDS Patents.

2.4. **Limitations on Agreement Not to Sue.** The obligations of SDS and Chembio under Section 2.2 and 2.3, or any other provisions in this Agreement, shall not extend to any product that is not an HIV Barrel Product, including any product in the Barrel Field for the detection or diagnosis of any target other than HIV.

3. **Agreements and Obligations of the Parties.**

3.1. **Patent Validity.** Chembio, having investigated and analyzed the SDS Patents during the course of the Pending Litigation, hereby acknowledges that each of the SDS Patents is valid and enforceable.

3.2. **No Validity Challenge.**

(a) Chembio agrees not to (and to cause its Affiliates not to) Challenge Patent Rights in the SDS Patents, or to assist any Third Party in doing so.

(b) SDS agrees not to (and to cause its Affiliates not to) Challenge any Patent Rights included in the Chembio IP or to assist any party in doing so, unless such Patent Rights are enforced or threatened to be enforced against SDS or an SDS customer or partner for infringement resulting from an SDS product or service other than a product in the Barrel Field that diagnoses or detects HIV or HIV infection which SDS product or service is sold in violation of this Agreement or the 3-Way Agreement. SDS further agrees not to challenge Chembio's right to continued use for manufacture of the HIV Barrel Product of the Confidential Information or Technology utilized by Chembio in the manufacture of the HIV Barrel Product.

3.3. **SDS/Chembio Manufacturing Agreement.** Effective upon execution of this Agreement, neither Party shall have any rights or obligations under the SDS/Chembio Manufacturing Agreement. Each Party hereby irrevocably releases the other Party with respect to any prior breach of the SDS/Chembio Manufacturing Agreement.

4. **Press Release.**

The parties agree that each will issue, in its customary fashion, a press release in mutually agreed form.

5. **Representations and Warranties.**

5.1. **Corporate Power.** Each Party represents to the other Party that it has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof. Each Party represents to the other that this Agreement constitutes a valid and binding agreement, enforceable against it in accordance with its terms.

5.2. **No Default or Violation.** Each Party represents and warrants to the other Party that the execution, delivery and performance of this Agreement does not (i) violate or require any registration, qualification, consent, approval, or filing under, (1) any law, statute, ordinance, rule or regulation, or (2) any judgment, injunction, order, writ or decree of any court, arbitrator, or governmental entity by which such Party or any of its assets or properties may be bound or (ii) except in the case of the Existing SDS Agreements and the Existing Chembio Agreements,

conflict with, require any consent, approval, or filing under, result in the breach or termination of any provision of, constitute a default under, result in the acceleration of the performance of any obligations under, result in the vesting or enhancement of any other Person's rights under, or result in the creation of any lien upon any of such Party's properties, assets, or businesses pursuant to (x) its organizing documents or By-Laws or (y) any material indenture, mortgage, deed of trust, license, permit, approval, consent, franchise, lease, contract, or other instrument or agreement to which such Party is a party or by which such Party or any of such Party's properties or assets is bound.

5.3. **Exclusion of Other Representations and Warranties.** EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY REPRESENTATIONS OR WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT. NEITHER PARTY WARRANTS THAT THE OTHER PARTY WILL RECEIVE ANY PARTICULAR AMOUNT, OR ANY, REVENUES OR PROFITS AS A RESULT OF ENTERING INTO THE BUSINESS ARRANGEMENTS DESCRIBED IN THIS AGREEMENT.

6. **General**.

6.1. **Term**. Unless otherwise terminated by agreement of the Parties, this Agreement shall continue in effect perpetually.

6.2. **Waivers and Amendments**.

(a) This Agreement may be amended, modified or supplemented only by a written instrument executed by the Parties hereto.

(b) No waiver of any provision of this Agreement, or consent to any departure from the terms hereof, shall be effective unless the same shall be in writing and signed by the Party waiving or consenting thereto. No failure on the part of either Party to exercise, and no delay in exercising, any right or remedy hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such right or remedy by such Party preclude any other or further exercise thereof or the exercise of any other right or remedy. The waiver by either Party hereto of a breach of any provision of this Agreement shall not operate as a waiver of any subsequent breach. All rights and remedies hereunder are cumulative and are in addition to and not exclusive of any other rights and remedies provided by law.

6.3. **Entire Agreement.** This Agreement and the Related Documents, including all schedules or attachments, taken together, constitute the entire agreement between the Parties hereto with respect to the subject matter hereof and supersede all prior agreements and understandings, whether written or oral, between the Parties in connection with such subject matter.

6.4. **Relationship of the Parties**. This Agreement shall not constitute either Party the agent or legal representative of the other Party for any purpose whatsoever, and neither Party shall hold itself out as an agent of the other Party. This Agreement creates no relationship of joint venturers, partners, associates, employment or principal and agent between the Parties, and each of the Parties is acting as an independent contractor. Neither Party is granted herein any right or authority to, and shall not attempt to, assume or create any obligation or responsibility for or on behalf of the other Party. Neither Party shall have any authority to bind the other Party to any contract.

6.5. **Notices**. All notices and other communications hereunder shall be in writing and shall be deemed given if delivered personally, telecopied (with confirmation) or mailed by registered or certified mail (return receipt requested) or delivered by recognized courier service providing evidence of delivery to the Parties at the following addresses:

(a) if to Chembio, to:

Chembio Diagnostic Systems, Inc.
3661 Horseblock Road
Medford, New York 11763
Attention: Lawrence A. Siebert, President
Telecopier No.: (631) 924-6033

with a copy to:

Ruskin Moscou Faltischek, P.C.
1425 Reckson Plaza
15th Floor, East Tower
Uniondale, New York 11556
Attention: Michael L. Faltischek, Esq,
Telecopier No.: (516) 663-6640

(b) if to SDS, to:

StatSure Diagnostic Systems, Inc.
One Clark's Hill
Framingham, MA 01702
Attention: Chief Executive Officer
Telecopier No.:

with a copy to:

Mintz, Levin, Cohn, Ferris,
Glovsky and Popeo, P.C.
One Financial Center
Boston, MA 02111
Attention: Jeffrey M. Wiesen, Esq.
Telecopier No.: 617-542-2241

or at such other address for a Party as shall be specified by like notice.

6.6. **Governing Law**. This Agreement shall be governed by, and construed and enforced in accordance with, the substantive laws of the State of New York, without giving effect to its conflicts of laws rules.

6.7. **Counterparts**. This Agreement may be executed in two or more counterparts, all of which shall be considered one and the same agreement and shall become effective when two or more counterparts have been signed by each of the Parties and delivered to the other Party, it being understood that both Parties need not sign the same counterpart. Facsimile execution and delivery of this Agreement by either of the Parties shall be legal, valid and binding execution and delivery of such document for all purposes.

6.8. **Further Assurances**. Each Party agrees to execute, acknowledge and deliver such further instructions, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

6.9. **Dispute Resolution.** In the event of any dispute or disagreement between the Parties as to the interpretation of any provision of this Agreement or the performance of any obligations hereunder, the matter, upon written request of either Party, shall be referred to **[mediation and]** arbitration in accordance with the procedures set forth in Schedule F to this Agreement.

6.10. **Injunctive Relief.** Each Party acknowledges that any breach or threatened breach of any of the terms and/or conditions set forth in this Agreement will result in substantial, continuing and irreparable injury to the other Party. Therefore, each Party hereby agrees that, in addition to any other remedy that may be available to the other Party, the other Party shall be entitled to injunctive or other equitable relief by a court of appropriate jurisdiction in the event of any breach or threatened breach of the terms of this Agreement.

6.11. **Assignment**. This Agreement is personal to each of the Parties, and neither Party shall assign any of its rights or delegate any of its obligations hereunder without the prior written consent of the other Party, which consent may be withheld for any reason, provided, however, that without the consent of the other Party, each Party may (i) assign its rights under this Agreement and delegate its obligations hereunder, in whole or in part, to any Person that shall acquire the business of such Party to which this Agreement relates, or to any Affiliate of such Party, if the assignee shall assume such Party's obligations hereunder in writing, and (ii) assign this Agreement in connection with a sale or transfer of substantially all of the assets of, or a majority interest in the voting shares of, such Party or its corporate parent to, or the merger or consolidation of such Party or its corporate parent with or into, any other Person.

IN WITNESS WHEREOF, the Parties have executed, or caused their duly authorized representatives to execute, this Agreement under seal as of the date first written above.

Chembio Diagnostic Systems, Inc.

By:

Title:

StatSure Diagnostic Systems, Inc.

By:

Title:

Exhibit A

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

----------x

:

CHEMBIO DIAGNOSTIC SYSTEMS INC. :

:

Plaintiff, :

v. : Civil Action No. 04-CV-1149-JS-ETB

SALIVA DIAGNOSTIC SYSTEMS INC. :

:

Defendant. :

:

----------x

STIPULATION OF DISMISSAL

It is hereby stipulated, by and between the parties through their respective counsel, that that above litigation, and all claims and counterclaims asserted therein, is hereby dismissed. Such dismissal shall be with prejudice with respect to the claims of the Plaintiff and without prejudice with respect to the counterclaims of the Defendant, all pursuant to and subject to the terms and conditions of a Settlement Agreement dated September 29, 2006.

Each party shall bear its own costs and fees arising out of or related to this action.

[signatures to be inserted]

TRA 2203497v.3

FOR IMMEDIATE RELEASE

Contacts: For Inverness: Doug Guarino 781647 3900; For Chembio: James Carbonara, The Investor Relations Group 212-825-3210; For StatSure: Investor Relations 508 872 2625

Inverness Medical Innovations, Chembio Diagnostics, Inc. and StatSure Diagnostic Systems, Inc. Announce Agreements to Market Rapid HIV and Other Tests

WALTHAM, MA; MEDFORD, NY; FRAMINGHAM, MA; October 5, 2006 - Inverness Medical Innovations, Inc. (Amex: IMA), Chembio Diagnostics, Inc. (OTCBB:CEMI), and StatSure Diagnostic Systems, Inc. (OTCBB: SSUR) announced today that they had entered into a series of agreements that provide Inverness with exclusive worldwide marketing rights to Chembio's FDA-cleared, point of care, rapid test for the detection of antibodies to HIV. The test utilizes Inverness' proprietary lateral flow technology as well as StatSure's patented "barrel" technology designed to maximize ease of use and minimize exposure to infectious agents.

In addition, Inverness obtains exclusive US marketing rights to Chembio's proprietary lateral flow cassette test (HIV 1/2 STAT PAK(TM)) for antibodies to HIV which will complement Inverness' market-leading Determine rapid HIV test (only sold outside the U.S.). In conjunction with this agreement, Chembio and StatSure will equally share in the profits relating to the application of the barrel technology and have settled past litigation between them. Details of this settlement are being announced separately.

Both Chembio HIV tests are FDA-cleared for use with fingertip blood, whole blood, serum or plasma for the detection of HIV-I as well as HIV-II antibodies. The proprietary barrel format has been designed to provide distinctive customer benefits relating to convenience, safety and product performance. Both tests achieved a sensitivity of 99.7% and a specificity of 99.9% in clinical trials.

Inverness also has granted Chembio a license to its lateral flow technology to manufacture and market the Chembio cassette HIV product and a Chembio dipstick HIV test outside the US and to manufacture and market certain defined veterinary and emerging disease tests. Inverness will also receive non-exclusive worldwide marketing rights under Inverness brands to this latter group of products and has invested $2 million in a Chembio financing as announced separately today. In addition, Inverness will also grant to SDS a license to its lateral flow technology for an HIV cassette product as well as certain other products.

The addition of two new HIV products, the FDA-cleared "barrel" and cassette formats, further strengthens the Inverness line of point of care testing products, already one of the broadest in the market. Rapid HIV testing is an expanding area with strong growth potential in Inverness's key markets of physician office and hospital testing as well as having the potential to be sold through retail channels. The HIV products will be introduced in the US as soon as FDA clearance is received for the use of Inverness labeling.

Commenting on the agreements, Ron Zwanziger, CEO of Inverness, said, "We are very pleased to be able to work with Chembio and StatSure to market these products. The recently published revised HIV testing recommendations from the CDC point to the need for screening all adults aged 13-64 as well as for routine testing for pregnant women and persons at high risk of infection."

Lawrence Siebert, President of Chembio commented, "This is a significant milestone for our company as we believe Inverness will be able to achieve widespread distribution of our products. We look forward to working with Inverness and StatSure on the barrel product and HIV cassette in the US, and capitalizing on the licenses we have received."

Steve Peltzman, CEO of StatSure commented, "Great technology, when married to outstanding manufacturing and Inverness' marketing, can produce extraordinary results. We believe this team will deliver those results as customers around the world recognize their needs for rapid HIV testing are best served by these new product entries."

ABOUT INVERNESS MEDICAL
Inverness Medical Innovations is a leading global developer of advanced diagnostic devices and is presently exploring new opportunities for its proprietary electrochemical and other technologies in a variety of professional diagnostic and consumer-oriented applications including immuno-diagnostics with a focus on women's health, cardiology and infectious disease. The Company's new product development efforts, as well as its position as a leading supplier of consumer pregnancy and fertility/ovulation tests and rapid point-of-care diagnostics, are supported by the strength of its intellectual property portfolio. Inverness is headquartered in Waltham, Massachusetts. For more information about Inverness Medical Innovations, please visit our website at http://www.invernessmedical.com.

ABOUT CHEMBIO
Chembio Diagnostics, Inc. (OTCBB: CEMI), a developer and manufacturer of rapid diagnostic tests for infectious diseases, is on the frontlines of the global battle against the AIDS pandemic. The Company has received marketing approval from the FDA for its SURE CHECK(R) HIV 1/2 and HIV 1/2 STAT-PAK(TM) rapid tests. The Company also manufactures rapid tests for veterinary Tuberculosis and Chagas Disease, and has developed a patent-pending technology, the Dual Path Platform (DPP(TM)), for its next generation HIV and other rapid tests. For additional information please visit www.chembio.com. Chembio has scheduled an investor web cast and conference call for Tuesday October 10, 2006 at 4:30 pm EDT to discuss these transactions as well as its recent financing. Details to follow in a subsequent press release.

ABOUT STATSURE
StatSure Diagnostic Systems, Inc. (OTCBB: SSUR) is engaged in the development, manufacture and marketing of rapid immunoassay tests for the detection of sexually transmitted and other infectious diseases; in addition, the Company has developed and is marketing a product line of patented, oral- fluid collection devices. The Company's proprietary platforms provide significant customer benefits and competitive advantages as compared to similar products that are currently available. Improved accuracy, operator convenience, and reduced risk of infection from collecting and handling specimens, have been engineered into SDS products. All of the company's diagnostic tests are based on the same easy-to-use technology platform, thus facilitating the development of future products. Certain of these products are sold in the United States as well as internationally to various distributors for use in clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations. Please visit our website at http://www.StatSure.com

This press release may contain forward-looking statements within the meaning of the federal securities laws. These statements reflect the parties' current views with respect to future events and are based on management's current assumptions and information currently available. Actual results may differ materially due to numerous factors, including without limitation, the future demand for HIV testing products; Inverness' ability to successfully commercialize the products; the intensely competitive environment in the relevant markets and the risks and uncertainties described in periodic reports filed by each of the parties with the Securities and Exchange Commission under the federal securities laws, including their periodic reports on Form 10-Q or Form 10-QSB, as applicable, for the period ended June 30, 2006. The parties undertake no obligation to update any forward-looking statements contained herein.

FOR IMMEDIATE RELEASE

StatSure and Chembio Agree to End Litigation and Enter Agreement to Commercialize HIV Barrel Technology

Contact: For Chembio: James Carbonara, The Investor Relations Group 212-825-3210; For StatSure: Investor Relations 508-872-2625

MEDFORD, NY; FRAMINGHAM, MA; October 5, 2006 - StatSure Diagnostic Systems, Inc. (OTCBB: SSUR) and Chembio Diagnostics, Inc. (OTCBB:CEMI) announced today that they have entered into a series of agreements that provide Inverness Medical Innovations, Inc. (AMEX:IMA) with exclusive worldwide marketing rights to Chembio's FDA-cleared, point of care, rapid, SURE CHECK(R) HIV 1/2 product for the detection of HIV 1 & 2 antibodies. This test utilizes StatSure's patented barrel technology, designed to provide convenient, safe, accurate and integrated single-use, rapid HIV antibody screening, and to minimize exposure to infectious agents; it will be exclusively manufactured by Chembio for Inverness' distribution.

Chembio and StatSure have entered into a Settlement Agreement pursuant to which all matters in their litigation regarding SDS' barrel patent and other matters have been settled. The Settlement Agreement, which is related to the parties' three-way agreements with Inverness (details of these agreements are being announced separately), provides that Chembio and StatSure will equally share the profits, and that they will act jointly in the HIV barrel field towards commercializing this technology and its ensuing products for the HIV market. The settlement combines each company's HIV barrel intellectual property, including an exclusive manufacturing license from StatSure to Chembio of its barrel patent for all HIV applications.

Recently the CDC formally issued new recommendations for routine HIV testing for all Americans between the ages of 13 and 64. Chembio anticipates receiving a CLIA (Clinical Laboratory Improvement Act) waiver from the FDA for these products soon, which will greatly expand the number of potential professional sites at which these tests could be performed.

Chembio's SURE CHECK(R) HIV 1/2 product is approved for use with finger-stick or venous whole blood, plasma, and serum, and has sensitivity and specificity performance specifications of 99.7% and 99.9% respectively; furthermore these HIV products have a twenty-four month shelf life, which is substantially longer than competing products. SDS' patented barrel technology enables convenient, direct collection of a whole blood sample from the finger tip without need for a separate sample transfer device. This format also results in a closed system designed to reduce exposure to potentially infectious material.

Lawrence Siebert, President of Chembio commented, "We are pleased to end the litigation with StatSure and enter this new agreement so that we can deploy our capital more productively. We look forward to working together with StatSure and Inverness to capitalize on the significant global opportunity for the HIV barrel product."

Steve Peltzman, President of StatSure commented, "Litigation is always a time-consuming, expensive win-lose battle. Our Settlement represents an authentic win-win-win for each of the parties involved and certainly jump starts our ability to commercialize this important technology. We now are partners in the HIV Barrel Field and intend to add and receive significant value to and from this strategic relationship."

ABOUT CHEMBIO

Chembio Diagnostics, Inc. (OTCBB: CEMI), a developer and manufacturer of rapid diagnostic tests for infectious diseases, is on the frontlines of the global battle against the AIDS pandemic. The Company has received marketing approval from the FDA for its SURE CHECK(R) HIV 1/2 and HIV 1/2 STAT-PAK(TM) rapid tests. The Company also manufactures rapid tests for veterinary Tuberculosis and Chagas Disease, and has developed a patent-pending technology, the Dual Path Platform (DPP(TM)), for its next generation HIV and other rapid tests. For additional information please visit www.chembio.com. Chembio has scheduled an investor web cast and conference call l for Tuesday October 10, 2006 at 4:30 pm EDT to discuss these transactions as well as its recent financing. Details to follow in a subsequent press release.

ABOUT STATSURE

StatSure Diagnostic Systems, Inc. (OTCBB: SSUR) is engaged in the development, manufacture and marketing of rapid immunoassay tests for the detection of sexually transmitted and other infectious diseases; in addition, the Company has developed and is marketing a product line of patented, oral- fluid collection devices. The Company's proprietary platforms provide significant customer benefits and competitive advantages as compared to similar products that are currently available. Improved accuracy, operator convenience, and reduced risk of infection from collecting and handling specimens, have been engineered into SDS products. All of the company's diagnostic tests are based on the same easy-to-use technology platform, thus facilitating the development of future products. Certain of these products are sold in the United States as well as internationally to various distributors for use in clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations. Please visit our website at http://www.StatSure.com

This press release may contain forward-looking statements within the meaning of the federal securities laws. These statements reflect the parties' current views with respect to future events and are based on management's current assumptions and information currently available. Actual results may differ materially due to numerous factors, including without limitation, the future demand for HIV testing products; Inverness' ability to successfully commercialize the products; the intensely competitive environment in the relevant markets and the risks and uncertainties described in periodic reports filed by each of the parties with the Securities and Exchange Commission under the federal securities laws, including their periodic reports on Form 10-Q or Form 10-QSB, as applicable, for the period ended June 30, 2006. The parties undertake no obligation to update any forward-looking statements contained herein.