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): May 14, 2015

Atossa Genetics Inc.

(Exact name of registrant as specified in its charter)

Delaware	001-35610	26-4753208
(State or other jurisdiction of	(Commission File Number)	(I.R.S. Employer
incorporation)		Identification No.)
2345 Eastlake Ave. East, Suite 201		
Seattle, Washington		98102
(Address of principal executive offices	<u> </u>	(Zip Code)

Registrant's telephone number, including area code: (206) 325-6086

Not Applicable

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:

- o 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)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01. Entry into Material Definitive Agreement

On May 14, 2015, the Atossa Genetics Inc. ("Atossa") entered into an Intellectual Property License Agreement (the "Agreement") with Besins Healthcare Luxembourg SARL ("Besins"). The Agreement provides Atossa with an exclusive worldwide license to develop and commercialize Besins' patented gel formulation of 4-Hydroxytamoxifen, or Afimoxifene Gel, for the potential treatment and prevention of hyperplasia of the breast.

The Agreement requires that Atossa pay a royalty of 8% to 9% of net sales for the first 15 years of commercialization. Atossa has the non-exclusive right to also develop Afimoxifene Gel for breast cancer and other breast diseases, subject to the payment of the following milestone payments for these additional indications: (i) \$5,000,000 for the exclusive right to review, access, and reference a Besins investigational new drug application (IND) for each additional indication, and (ii) \$20,000,000 when Atossa commences a Phase 3 clinical trial for each additional indication.

If and when Atossa decides to sublicense its rights to commercialize the Afimoxifene Gel in a country in the territory, Besins has the right of first refusal to commercialize the Afimoxifene Gel on a country-by-country basis in countries where Besins has a marketing presence.

The Agreement automatically expires on a country-by-country basis fifteen years after the first commercial sale of Afimoxifene Gel in the particular country. The Agreement may be terminated (i) by either party upon a material breach of the Agreement that is not cured by the breaching party, (ii) by mutual agreement of the parties, (iii) by Atossa at its discretion if it elects to stop developing or commercializing Afimoxifene Gel, (iv) by Besins on a country-by-country basis or indication-by-indication basis if Atossa fails to commercialize or commercial sales within a specified time, or (v) by Besins if Atossa fails to accomplish any aspect of the development plan within six months of target date set forth in the development plan. The development plan covers an 18-month period and is required to be updated by Atossa every six months during the term of the Agreement.

Item 9.01. Financial Statements and Exhibits

Exhibits

10.1 Intellectual Property License Agreement between Atossa Genetics Inc. and Besins Healthcare Luxembourg SARL, dated May 14, 2015.

* * *

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 hereunto duly authorized.

Date: May 18, 2015 Atossa Genetics Inc.

By: /s/ Kyle Guse

Kyle Guse

Chief Financial Officer, General

Counsel and Secretary

INTELLECTUAL PROPERTY LICENSE AGREEMENT

This INTELLECTUAL PROPERTY LICENSE AGREEMENT (this "Agreement") is entered into as of May 14, 2015 (the "Effective Date"), by and between ATOSSA GENETICS INC., a Delaware Corporation, with its principal offices located at 2345 Eastlake Ave E., Seattle, WA 98102, U.S.A. ("Atossa"), and BESINS HEALTHCARE LUXEMBOURG SARL., a corporation, with its principal office located at 2-8 rue Julien Vesque, L-2668 Luxembourg, acting on behalf of itself and its Affiliates (collectively "Besins"). Atossa and Besins may be referred to herein individually as a "Party" or collectively as the "Parties."

RECITALS

WHEREAS, the Parties are engaged in the research, development, formulation, manufacturing, and marketing of new pharmaceutical products;

WHEREAS, Atossa desires to obtain certain rights and licenses from Besins in order to develop, formulate, manufacture, and market new pharmaceutical products on the terms and conditions set forth herein;

WHEREAS, Besins desires to grant certain rights and licenses to Atossa to enable Atossa to develop, formulate, manufacture, and market new pharmaceutical products on the terms and conditions set forth herein; and

NOW, THEREFORE, in consideration of the mutual promises hereinafter set forth, and intending to be legally bound hereby, Atossa and Besins hereby agree as follows.

ARTICLE 1 Defined Terms

- 1.1 **General**. Capitalized terms and expressions in this Agreement will have the meanings set forth herein, whether used in their singular or plural form. Noncapitalized terms and expressions will have their common and ordinary meaning.
- 1.2 "Action" shall have the meaning set forth in Section 3.2(b).ii.b.
- 1.3 "Additional Indication" means (i) breast cancer and (ii) other breast diseases described in Besins Core IP or Besins Regulatory Information.
- 1.4 "Affiliate" means, with respect to a Party, a corporation, partnership or other entity controlling, controlled by or under common control with such Party, but only for so long as such relationship exists, where the word "control," as used in this Section 1.4, means ownership, directly or indirectly, of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors or, in the case of a non-corporate entity, the power to direct the management of such entity.

- 1.5 "**Afimoxifene Gel**" means API in the form of a hydroalcoholic gel or solution that is formulated for dosing a mammal. "**Besins Afimoxifene Gel**" means any Afimoxifene Gel described in Besins Platform IP or Besins Core IP, whether or not encompassed by a Valid Claim thereof.
- 1.6 "Agreement" shall have the meaning set forth in the preamble to this Agreement.
- 1.7 "API" means 4-Hydroxytamoxifen (4-OHT). For clarity, the term "API" includes the E-isomer form of 4-OHT, and the Z-isomer form of 4-OHT, either alone or in a combination thereof.
- 1.8 "Applicable Law" means all international, national, state, regional and local laws, regulations, rules and guidelines applicable to performing under this Agreement, including without limitation, all Regulatory Requirements.
- 1.9 "Atossa Background IP" means all Intellectual Property conceived, discovered, developed, acquired, made, reduced to practice, owned or Controlled by or for Atossa or an Affiliate thereof before the Effective Date. For clarity, Atossa Background IP includes (i) any patent claiming Afimoxifene Gel as described in Exhibit A and any patent issuing from a pending patent application claiming Afimoxifene Gel as described in Exhibit A, such Exhibit A shall be a part of this Agreement; (ii) any continuation or divisional patents and patent applications based on, corresponding to, or claiming the priority date(s) of the foregoing (i); (iii) any reissues, re-examinations, substitutions, supplementary protection certificates, registrations, validations, continued prosecutions, continuations or divisions of or to any of the foregoing (i) (ii); (iv) any continuation-in-part of or to any of the foregoing (i) (iii) wherein any added material in the continuation-in-part does not claim any Besins Afimoxifene Gel or the use of any Afimoxifene Gel in the Field; (v) any term extension or other right which provides exclusive rights beyond the original patent expiration date of the foregoing (i) (iv); and (vi) all foreign counterparts of any of the foregoing (i)-(v), whether filed before or after the Effective Date. For avoidance of doubt, all Intellectual Property conceived discovered, developed, acquired, made, or reduced to practice by or for Atossa or an Affiliate thereof, which does not claim any Besins Afimoxifene Gel or the use of any Afimoxifene Gel in the Field, shall not be considered Atossa Foreground IP; such Intellectual Property shall be Background IP regardless of when it was conceived, discovered, developed, acquired, made, or reduced to practice.
- 1.10 "Atossa Foreground IP" means all Intellectual Property claiming any Besins Afimoxifene Gel or claiming any uses of any Afimoxifene Gel in the Field conceived, discovered, developed, made or reduced to practice by or for Atossa or an Affiliate thereof during the Term in connection with obtaining Regulatory Approval, Development, and/or Commercialization of Afimoxifene Gel in the Field, including (i) any new patent applications and issued or granted patents claiming any Besins Afimoxifene Gel or the use of any Afimoxifene Gel in the Field filed or authorized to be filed by or for Atossa or an Affiliate thereof, (ii) any new patent applications and issued patents based on, corresponding to, or claiming the priority date(s) of the foregoing (i); (iii) any reissues, re-examinations, substitutions, supplementary protection certificates, registrations, validations, continuations, continued prosecutions, divisions, or continuations-in-part of or to any of the foregoing (i) (ii), to the extent any such continuation-in-part claims any Besins Afimoxifene Gel or the use of any Afimoxifene Gel in the Field; (iv) any term extension or other right which provides exclusive rights beyond the original patent expiration date of any of the foregoing (i) (iii); and (v) all foreign counterparts of any of the foregoing (i) (iv). For clarity, Atossa Foreground IP may include claims in continuations-in-part of Atossa Background IP if any added claims in such continuation-in-part describes any Besins Afimoxifene Gel or the use of any Afimoxifene Gel in the Field. Atossa Foreground IP does not include any Atossa Background IP, Atossa Regulatory Information or Atossa Know-How owned or Controlled by Atossa or an Affiliate thereof, Besins Core IP, Besins Platform IP, or Regulatory Information or Know-How owned or Controlled by Besins or an Affiliate thereof before the Effective Date. Atossa Foreground IP shall be listed in an Exhibit B, such Exhibit B shall become of this Agreement and be updated biannually.

- 1.11 "Atossa Indemnitees" shall have the meaning set forth in Section 9.2.
- 1.12 "**Besins Core IP**" means all Intellectual Property directed to the use of Afimoxifene Gel in the Field and Controlled by Besins or an Affiliate thereof before the Effective Date. For clarity, Besins Core IP includes (i) any patents described in **Exhibit C** and any patents issuing from a pending patent application described in **Exhibit C**, which shall be a part of this Agreement and be updated bi-annually; (ii) any continuation, continuation-in-part, or divisional patents and patent applications based on, corresponding to, or claiming the priority date(s) of the foregoing (i); (iii) any reissues, re-examinations, substitutions, supplementary protection certificates, registrations, validations, continued prosecutions, continuations, continuations-in-part, or divisions of or to any of the foregoing (i) (ii); (iv) any term extension or other right which provides exclusive rights beyond the original patent expiration date of the foregoing (i) (iii); and (v) all foreign counterparts of any of the foregoing (i) (iv), whether filed before or after the Effective Date.

1.13 "Besins Platform IP" means any Besins Intellectual Property directed to Afimoxifene Gel and Controlled by Besins or an Affiliate thereof before the Effective Date. For clarity, Besins Platform IP includes (i) any patents described in **Exhibit D** and any patents issuing from a pending patent application described in **Exhibit D**, which shall be a part of this Agreement and be updated bi-annually; (ii) any continuation, divisional or continuation-in-part patents and patent applications based on, corresponding to, or claiming the priority date(s) of the foregoing (i); (iii) any reissues, re-examinations, substitutions, supplementary protection certificates, registrations, validations, continued prosecutions, continuations, divisions or continuations-in-part of or to any of the foregoing (i) – (ii); (iv) any term extension or other right which provides exclusive rights beyond the original patent expiration date of the foregoing (i) – (iii); and (v) all foreign counterparts of any of the foregoing (i) – (iv), whether filed before or after the Effective Date.

- 1.14 "cGMP" means the current Good Manufacturing Practices as promulgated under the U.S. Food & Drug Administration regulations at 21 C.F.R., Parts 210, 211, 600 and 610, FDA guidance, FDA current review and inspection standards, and current industry standards, as the same may be amended or reenacted from time to time.
- 1.15 "Clinical Development" means clinical drug development activities with respect to, or required or necessary for, IND and/or Regulatory Approval of Afimoxifene Gel, or for Commercialization of Afimoxifene Gel, including, among other things: analytical, test method development, stability testing, formulation, process development, manufacturing scale-up, development stage manufacturing, pre-clinical studies, Clinical Studies (including pre- and post-approval clinical studies), and/or other studies or activities (including regulatory affairs and activities, quality assurance/control activities, and performance with respect to clinical materials, statistical analysis and report writing, product approval and product registration.
- 1.16 "Clinical Study" means a clinical research study involving human subjects, and for a Phase 2 Clinical Study, its principal purpose is determining dose and evaluating safety and efficacy of the Afimoxifene Gel in the target patient population, or a similar clinical study prescribed by the Regulatory Authority in the Territory, which is equivalent of the clinical trial described in 21 C.F.R. § 312.21(b), as may be amended, in the United States of America, and for a Phase 3 Clinical Study, it is designed to establish safety and efficacy of the Afimoxifene Gel, which trial is intended to support Regulatory Filing and Regulatory Approval for the Afimoxifene Gel in the Territory, as the case may be, and which is equivalent of the clinical trial described in 21 C.F.R. § 312.21(c), as may be amended, in the United States of America.
- 1.17 "Commercialize," "Commercialization" "Commercializing" or "Commercialized" means any and all activities relating to and including promotion, marketing, distribution, selling, having sold, offering for sale, having offered for sale, manufacturing, having manufactured, importing, having imported, exporting, having exported, and sales of Afimoxifene Gel in the Territory in accordance with Applicable Law, including advertising, product support, consumer and physician education, managed market activities, market share generation trials, market and consumer research, customer support, detailing, distributing, labeling, pricing, coverage, and reimbursement.

- 1.18 "Commercially Reasonable Efforts" means those efforts employed by a Party, consistent with that level of attention and care, and providing of funding and manpower, that such Party devotes to its other programs and products of similar market potential, and which efforts are consistent with pharmaceutical industry custom and practice and with the then-current stage of pharmaceutical product life cycle.
- 1.19 "Confidential Information" means any and all non-public data, information and technology and all tangible and intangible embodiments thereof, that is (i) Controlled by a Party or its Affiliates ("Disclosing Party") and is disclosed or supplied in any form by or on behalf of such Disclosing Party to the other Party or its Affiliates ("Receiving Party") in any media or format, whether written, oral, graphic, or other tangible form or electronic form, in connection with this Agreement or otherwise observed by the Receiving Party, and (ii) is not published or otherwise in the public domain, including, without limitation: (a) Intellectual Property, Data and Development Records of a Party; (b) information or material provided in written, oral, graphic or other tangible form or electronic form that is marked as "Confidential" at the time it is delivered to the Receiving Party or confirmed and marked as "Confidential" within thirty days after disclosure; and (c) any information or material that, by its nature or by the circumstances surrounding its disclosure, ought, in good faith, to be treated as confidential.
- 1.20 "Control" when used in reference to a particular item of information (including Information) or Intellectual Property right, means the legal authority or right of a Party (i) to grant a license or sublicense of Intellectual Property rights to the other Party, or (ii) to grant access and/or a right to use, or to otherwise disclose, proprietary or Trade Secret Information to the other Party, without breaching the terms of any agreement with a Third Party, infringing upon the Intellectual Property rights of a Third Party, or misappropriating the proprietary or Trade Secret Information of a Third Party, and without incurring material additional costs to procure such Third Party rights beyond those already incurred. The terms "Controlled" and "Controlling" shall be interpreted accordingly.
- 1.21 "**Data**" means any and all analyses, computations, charts, computer or device readings or outputs, data, diagrams, graphs, information, results (whether qualitative, quantitative, or otherwise) pertaining to Afimoxifene Gel and obtained or produced by or for either Party, its officers, directors, employees, subcontractors, agents and Affiliates, together with all documentation thereof.
- 1.22 "Development," "Develop," or "Developing" means to engage in Pre-Clinical Development or Clinical Development of Afimoxifene Gel.

- 1.23 "**Development Plan**" means Atossa's plan for Developing Afimoxifene Gel in the Field in the Territory under this Agreement as amended, modified, or supplemented from time to time by Atossa in good faith, and includes Development milestones and periods for accomplishing those milestones in accordance with industry standards. Atossa's Development Plan is listed in Appendix E, which shall be part of this Agreement.
- 1.24 "Development Record" means all documentation that is owned or Controlled by a Party (e.g., "Besins Development Record" or "Atossa Development Record") that relates to Data and/or to performance of Development and Commercialization of Afimoxifene Gel and necessary to support the filing of patent and/or regulatory application(s) and to obtain Regulatory Approval of and Commercialize Afimoxifene Gel in the Field including, without limitation, all applications, submissions, licenses, registrations for Regulatory Approval, know-how, primary source documents, testing results, manufacturing records including manufacturing designs and protocols, compliance and quality assurance documents, research notes and records, Clinical Development notes and records, regulatory filings and communications, including without limitation, any INDs and NDAs related to Afimoxifene Gel, drug master files, packaging and labeling information, clinical trial protocols and amendments thereof, investigator brochures, safety reports, annual reports, raw data, and other related Development records regardless of format or media.
- 1.25 "Effective Date" shall have the meaning set forth in the preamble.
- 1.26 "**Encumbered**" means any encumbrance or restriction on the right of Besins to grant a license to the full extent described in <u>Sections 2.1</u> of this Agreement, as applicable, that was (i) licensed by Besins to a Third Party under an agreement executed prior to the Effective Date, or (ii) subject to a security interest or lien.
- 1.27 "Field" initially means the treatment and prevention of Hyperplasia of the breast, and may be expanded to include one or both Additional Indications in accordance with Section 4.2 of this Agreement.
- 1.28 "First Commercial Sale" means the first arm's length commercial sale of Afimoxifene Gel in the Territory to a Third Party by Atossa, or its Affiliate or Sublicensees, after Regulatory Approval has been obtained in the country of sale, but excluding: (i) any sale or other transfer of a Afimoxifene Gel by Atossa or any of its Affiliates or Sublicensees to a Third Party for use solely in Clinical Trial(s) in connection with obtaining Regulatory Approval; and (ii) any sale or other transfer between or among Atossa and its Affiliates or its Sublicensees for resale by Atossa, such Affiliate or Sublicensee to a Third Party, until such time as there is a subsequent resale to a Third Party by Atossa or any such Affiliate or Sublicensee.

- 1.29 "Force Majeure" means any event beyond the reasonable control of a Party, including, acts of public enemy, acts of God, fires, floods, epidemics, and unusually severe weather, embargoes, war, riot, or acts of terrorism.
- 1.30 "**IND**" means (i) an Investigational New Drug Application, as defined in the U.S. Federal Food, Drug and Cosmetic Act, as amended, and the regulations promulgated thereunder, that is required to be filed with the FDA before beginning clinical testing of a pharmaceutical product in human subjects; and (ii) any foreign counterpart of a U.S. IND.
- 1.31 "Indication" shall mean any human therapeutic and prophylactic use(s) for Afimoxifene Gel.
- 1.32 "Intellectual Property" means (i) Know-How, (ii) any (a) patents and patent applications, (b) any reissues, re-examinations, substitutions, supplementary protection certificates, registrations, validations, continuations, continuations-in-part, continued prosecutions, or divisions of or to any of the foregoing (a); (c) any term extension or other right which provides exclusive rights beyond the original patent expiration date of any of the foregoing (a) (b); and (d) all foreign counterparts of any of the foregoing (a) (c), whether filed before or after the Effective Date, (iii) any information, data, know-how, invention (whether patentable or not), technology, techniques, Development Records, Manufacturing Information, and Regulatory Information that derives actual or potential economic value from not being generally known to or readily ascertainable by proper means by other persons who can obtain economic value from its disclosure or use and is the subject of reasonable efforts to maintain its secrecy; (iv) all Trade Secret-associated rights or protections granted under applicable laws of the United States, applicable state laws, and/or applicable laws in foreign jurisdictions; and (v) all other intellectual property and proprietary rights, including Copyrights, Trade Dress, and Trademarks, in each case whether or not subject to statutory registration or protection.
- 1.33 "Losses" shall have the meaning set forth in Section 9.2.
- 1.34 "Know-How" means any proprietary or non-public information and/or data related to the Field, Afimoxifene Gel, or Regulatory Information, or which are otherwise necessary or useful to Development, Commercialization, or obtaining Regulatory Approval of Afimoxifene Gel for use in the Field, and which are possessed, known, learned, invented, developed, owned, or controlled by a Party (e.g., "Besins Know-How" or "Atossa Know-How"), whether or not protected by Intellectual Property rights or any applications for such rights, including but not limited to: (i) information relating to concepts, discoveries, Data, designs, technical information, know-how, knowledge, clinical data, formulations, ideas, inventions, methods, models, procedures, processes, specifications, designs for experiments and tests (including processing testing), test results, and assays; (ii) information related to identity, specification, release, stability indication of API, excipient, finished goods, rework criteria, batch records, suppliers, and laboratory records; (iii) information germane to making, using, selling, offering for sale, importing, exporting Afimoxifene Gel or practicing methods related to Afimoxifene Gel in the Field; and (iv) information contained in submissions to regulatory authorities.

1.35 "Manufacturing Information" means information, Data, Know-How, technology, techniques and any other information that is owned or Controlled by or for a Party (e.g., "Besins Manufacturing Information" or "Atossa Manufacturing Information") that relates to manufacturing of Afimoxifene Gel. Such manufacturing information includes, without limitation, all information related to GMP and cGMP protocols, development data, Development Records, pilot phase and commercial process development, scale up, qualification, calibration, maintenance, validation and testing protocols, specifications, and data, and includes information related to identity, specification, release, stability indication of API, excipient, formulation, finished goods, rework criteria, batch records, suppliers, and tangible materials, and true, accurate and complete books, records, reports and accounts in connection with the Afimoxifene Gel manufacturing as well as any other books and records as may be required from time to time by any applicable legal and regulatory requirement such as drug master files and regulatory audits, facility audits, audit reports, warning letters, and remediation activities and reports, and other regulatory communications regarding manufacturing activities.

1.36 "Net Sales" means the gross revenue received by Atossa, its Affiliates, their respective Sublicensees and Atossa Third-Party Resellers for the sale of Afimoxifene Gel to Third Parties other than Besins and its Affiliates and Sublicensees (whether end-users, wholesalers or otherwise) in an arm's-length transaction, less the amount of the following deductions: (i) normal and customary trade, cash and quantity discounts actually given, credits, price adjustments or allowances for damaged products, returns or rejections of products, and allowance or rebates for retroactive price reductions; (ii) chargeback payments and rebates (or the equivalent thereof), if any, granted to group purchasing organizations, managed health care organizations or to federal, state/provincial, local and other governments, including their agencies, or to trade customers, wholesalers or other distributors; (iii) freight, shipping insurance and other transportation expenses directly related to shipments or deliveries of Afimoxifene Gel (if actually borne by Atossa, its Affiliates or Sublicenses without reimbursement from any Third Party); (iv) sales taxes, value-added taxes, excise taxes, tariffs and duties of importation, and other taxes and any other similar government charges actually borne by Atossa, its Affiliates or Sublicensees in connection with the sale or delivery of Afimoxifene Gel without reimbursement from any Third Party (but not including taxes assessed against the income derived from such sale); and (v) provisions for actual uncollectible accounts determined in accordance with U.S. generally accepted accounting principles, International Financial Reporting Standards, or such other accounting practices as Atossa or its Affiliates or Sublicensees may, at their sole discretion, adopt, as consistently applied by Atossa, its Affiliates, or Sublicensees (as applicable).

- 1.37 "**NDA**" means a New Drug Application or similar application or submission filed with a Regulatory Authority in a country or a group of countries to obtain marketing approval for a Afimoxifene Gel in that country or in that group of countries.
- 1.38 "Pre-Clinical Development" means drug development activities, including toxicology studies, bioanalytical test method development, pre-formulation and formulation, process development, manufacturing design and scale up, quality assurance/control and performance with respect to studies and materials.
- 1.39 "**Regulatory Approval**" means any approval, authorization, license, permit or registration granted or issued by a Regulatory Authority necessary for, or that otherwise governs, the research and development, Clinical Study, manufacture, handling, use, storage, import, export, transport, distribution or Commercialization of Afimoxifene Gel, including without limitation, where applicable, labeling, pricing and/or reimbursement approval.
- 1.40 "**Regulatory Authority**" means, with respect to any particular country, territory or union, the governmental authority, body, commission, agency or other instrumentality of such country, territory or union with the primary responsibility for the evaluation or approval of pharmaceutical products before such pharmaceutical product may be tested, marketed, promoted, distributed or sold in such country, including such governmental bodies that have jurisdiction over the pricing of such pharmaceutical product.
- 1.41 "**Regulatory Information**" means information, data, know-how, technology, techniques, and any other information that is owned or Controlled by a Party (*e.g.*, "**Besins Regulatory Information**" or "**Atossa Regulatory Information**") that relates to Regulatory Approval of Afimoxifene Gel, including Data, practices, methods, techniques, preclinical and clinical results, including safety and efficacy, regulatory filings, IND, drug master files, regulatory audits and audit reports, warning letters, remediation activities, and remediation reports, packaging, compositions of matter, specifications, tests (including processing testing), assays, and methods. Besins Regulatory Information includes IND 59,081 and IND 66,076.
- 1.42 "**Regulatory Requirements**" means all applicable approvals, licenses, registrations, and authorizations and all other requirements of each applicable Regulatory Authority in relation to Afimoxifene Gel, including each of the foregoing which is necessary for, or otherwise governs, the research (clinical and non-clinical) and Development, manufacture, handling, use, storage, import, transport, distribution or Commercialization of Afimoxifene Gel.

- 1.43 "Sublicensee" means any Party or Third Party to which a Party has granted a sublicense under the licenses granted to the Party herein.
- 1.44 "**Supplier**" means any supplier operating under an agreement with a Party or an Affiliate or Sublicensee thereof (*e.g.* "**Atossa Supplier**" or "**Besins Supplier**") to manufacture or supply Afimoxifene Gel.
- 1.45 "**Term**" shall have the meaning set forth in <u>Section 8.1</u>.
- 1.46 "**Terminated Country**" means a country in the Territory wherein rights of Atossa granted hereunder have been terminated in accordance with <u>Section</u> <u>4.3(a)</u>, <u>4.3(b)</u>, <u>4.3(c)</u> or <u>4.3(d)</u>.
- 1.47 "**Terminated Indication**" means an Indication in the Field to which the rights granted to Atossa hereunder have been terminated in accordance with Section 4.3(a), 4.3(b), 4.3(c) or 4.3(d).
- 1.48 "Territory" means worldwide.
- 1.49 "Third Party" means any person or entity other than Atossa or Besins and their respective Affiliates.
- 1.50 "Third Party Action" shall have the meaning set forth in Section 3.2(b).iii.a.
- 1.51 "Third Party Resellers" means Sublicensees, Suppliers, and distributors engaged by a Party and/or its Affiliates and Sublicensees (*e.g.*, "Atossa Third Party Resellers" or "Besins Third Party Resellers") to distribute the Afimoxifene Gel.
- 1.52 "Valid Claim" means a claim of (a) an issued and unexpired patent (the term of such patent to include any term extension or other right which provides exclusive rights beyond the original patent expiration date) included within the Besins Core IP or Besins Platform IP unless the claim has been held revoked, unenforceable or invalid by the final, un-reversed, and un-appealable decision of a court or other body of competent jurisdiction, has been irretrievably abandoned or disclaimed, or has otherwise been finally admitted or finally determined by the relevant authority to be invalid, un-patentable or unenforceable, whether through reissue, reexamination, disclaimer, consent decree, or otherwise, (b) a pending patent application within the Besins Core IP or Besins Platform IP, to the extent the claim continues to be prosecuted in good faith, or (c) a pending patent application or issued patent within the Atossa Foreground IP that describes Besins Afimoxifene Gel or the use of any Afimoxifene Gel in the Field.

ARTICLE 2 License Grants

2.1 Besins Core IP, Besins Platform IP, and Afimoxifene Gel.

Subject to terms and conditions set forth in this Agreement, during the Term, Besins hereby grants to Atossa and its Affiliates:

- (a) an exclusive (even as to Besins and its Affiliates), transferable license (with the right to sublicense in accordance with Section 2.1(d) through multiple tiers under terms and conditions at least as restrictive as this Agreement) under Besins Core IP and under Besins Platform IP to make, have made, manufacture, have manufactured, use, sell, have sold, offer to sell, have offered to sell, import, have imported, export, have exported, and otherwise transfer, dispose of, distribute, or Develop and improve Afimoxifene Gel for the sole purposes of obtaining Regulatory Approval and Commercialization of Afimoxifene Gel in the Field in the Territory during the Term and practicing any method claimed in the Besins Core IP and Besins Platform IP in the Field in the Territory during the Term; and
- (b) a right to access, review and reference Besins IND 59,081 and IND 66,076 to the extent that such access, review, and reference may be useful to Develop Afimoxifene Gel for the sole purposes of obtaining Regulatory Approval and Commercialization of Afimoxifene Gel in the Field in the Territory, which right shall be exclusive in the Field in the Territory.
- (c) Notwithstanding the licenses granted under Section 2.1(a), Atossa acknowledges that Besins retains for itself and its Affiliates and Sublicensees the right to make, have made, manufacture, have manufactured, use, sell, have sold, offer to sell, have offered to sell, import, have imported, export, have exported, and otherwise transfer, dispose of, distribute, or Develop and improve Afimoxifene Gel for use outside the Field worldwide or for use in the Field on a Terminated Indication-by-Terminated Indication basis and/or in a Terminated Country. Atossa hereby recognizes that Besins or its Affiliates may establish a direct relationship with any Atossa Supplier with a prior ninety (90) business days' notice in writing to Atossa of its intent to do so and that Atossa may not take any action to restrict this right, *provided* that (i) Atossa Supplier provides written assurance to Besins that any relationship between Besins and Atossa Supplier shall not negatively impact the ability of Atossa Supplier to satisfy its supply obligations to Atossa, and (ii) Besins will ensure that any Afimoxifene Gel supplied to Besins by Atossa Supplier is labeled only for uses outside the Field. Further, for the same purpose, Besins shall be granted reasonable access from Atossa to any Afimoxifene Gel specifications, Data, Information and Development Records inclusive, as may be updated or modified from time to time during the Term, in reasonably completed and accurate form, and Besins shall treat the foregoing as Confidential Information pursuant to Article 6.

(d) <u>Sublicense(s)</u>: The term of the sublicenses hereunder granted by Atossa to Third Parties through multiple tiers shall be equal to the Term of this Agreement. In the event of any sublicense of any rights hereunder, the sublicensor of such rights shall provide Besins with written notice of, and a copy of the agreement memorializing such sublicense within thirty (30) days of execution of the sublicense. For any country of the Territory for which Commercialization has not been (or is not anymore) sublicensed by Atossa, Besins shall have a right of first refusal to Commercialize the Afimoxifene Gel in the Field during the Term on terms as least as favorable to Besins as Atossa or its Affiliates would offer to a Third Party, *provided however* that Besins has its own commercial operations of breadth, depth and scope equal to such Third Party and including having sufficient manpower in this country.

2.2 Atossa Foreground IP.

Subject to terms and conditions set forth in this Agreement, Atossa hereby grants to Besins and its Affiliates an irrevocable, perpetual, non-exclusive, royalty-free, fully paid, non-transferable license (with the right to sublicense through multiple tiers under terms and conditions at least as restrictive as this Agreement) under Atossa Foreground IP to make, have made, use, sell, have sold, offer to sell, have offered to sell, import, have imported, export, have exported, and otherwise transfer, dispose of, and distribute Afimoxifene Gel outside the Field worldwide or in the Field on a Terminated Indication-by-Terminated Indication basis and/or in a Terminated Country.

2.3 Covenants Not to Sue.

(a) Besins hereby covenants, on behalf of itself and its Affiliates, successors and assigns, not to sue or otherwise bring a claim against Atossa or its Affiliates or Atossa Third Party Resellers, during the Term, asserting that their conduct of the following activities infringes any Regulatory Information and/or Intellectual Property that is Controlled by Besins and not licensed to Atossa pursuant to this Agreement: (i) making, having made, manufacturing, having manufactured, using, selling, having sold, offering to sell, having offered to sell, importing, having imported, exporting, have exported, or otherwise transferring, disposing of, distributing, or Developing Afimoxifene Gel for the sole purposes of obtaining Regulatory Approval and Commercialization of Afimoxifene Gel for any Indication in the Field and practicing in the Field in the Territory any method using Afimoxifene Gel claimed by intellectual property that is Controlled by Besins and not licensed to Atossa pursuant to this Agreement. In addition to Atossa and its Affiliates, the covenant set forth in this Section 2.3(a) shall extend to (1) Third Parties, including Sublicensees and Atossa Suppliers, to whom Atossa has granted sublicenses to the rights obtained by Atossa under Section 2 of this Agreement, or who purchase or otherwise receive Afimoxifene Gel for use in the Field from Atossa consistent with the terms of this Agreement; (2) other of Atossa's Sublicensees of the rights obtained by Atossa under Section 2 of this Agreement, including Atossa Third Party Resellers and customers who receive Afimoxifene Gel for use in the Field in the Territory consistent with the terms of this Agreement; and (3) any successors and assigns of Atossa or Affiliates thereof.

(b) Atossa hereby covenants, on behalf of itself and its Affiliates, successors and assigns, not to sue or otherwise bring a claim against Besins or its Affiliates or Besins Third Party Resellers, during the Term, asserting that their conduct of the following activities infringes any Regulatory Information and/or Intellectual Property that is Controlled by Atossa and not licensed to Besins pursuant to this Agreement: (i) making, having made, manufacturing, having manufactured, using, selling, having sold, offering to sell, having offered to sell, importing, having imported, exporting, have exported, or otherwise transferring, disposing of, distributing, or Developing Afimoxifene Gel for the sole purposes of obtaining Regulatory Approval and Commercialization of any Besins Afimoxifene Gel for any Indication outside the Field worldwide or inside the Field on a Terminated Indication-by-Terminated Indication basis and/or in a Terminated Country and practicing any method using Besins Afimoxifene Gel outside the Field worldwide or inside the Field on a Terminated Indication-by-Terminated Indication basis and/or in a Terminated Country claimed by intellectual property that is Controlled by Atossa and not licensed to Besins pursuant to this Agreement, provided however, such conduct shall not infringe any Regulatory Information and/or Intellectual Property conceived, developed or Controlled by Atossa which does not claim Besins Afimoxifene Gel. In addition to Besins and its Affiliates, the covenant and restrictions set forth in this Section 2.3(b) shall extend to (1) Third Parties, including Sublicensees and Besins Suppliers, to whom Besins has granted sublicenses to the rights obtained by Besins under Section 2 of this Agreement, including Besins Third Party Resellers and customers who receive Besins Afimoxifene Gel consistent with the terms of this Agreement; and (3) any successors and assigns of Besins or Affiliates thereof.

2.4 No Implied Right or License.

Nothing contained in this Agreement will be implied to grant to one Party any ownership right or license right with respect to the other Party's Intellectual Property other than as expressly provided herein.

ARTICLE 3 Intellectual Property

3.1 Ownership.

(a) <u>Besins Intellectual Property.</u>

Notwithstanding the licenses granted hereunder, Besins shall retain sole and exclusive ownership of all rights, title, and interest in and to Besins Core IP and Besins Platform IP.

(b) <u>Atossa Background Intellectual Property.</u>

Atossa shall retain sole and exclusive ownership of all rights, title, and interest in and to Atossa Background IP at all times.

(c) <u>Atossa Foreground Intellectual Property.</u>

Notwithstanding the licenses granted hereunder, Atossa shall retain sole and exclusive ownership of all rights, title, and interest in and to Atossa Foreground IP.

3.2 **Protection of Intellectual Property.**

- (a) Patent Filing, Prosecution and Maintenance.
- i. Rights and Obligations of Besins

Besins shall retain the exclusive right, but not the obligation, to prepare, file, prosecute and maintain all registerable rights in the Besins Core IP and Besins Platform IP (collectively "Besins IP") at all times during the Term of this Agreement at the sole expense of Besins. Besins shall provide Atossa a reasonable and meaningful opportunity to review and comment on such patent preparation, filing, prosecution and maintenance related to the Besins Core IP and Besins Platform IP and shall consider such input from Atossa.

ii. Rights and Obligations of Atossa

Atossa shall have the exclusive right, but not the obligation, to prepare, file, prosecute, and maintain, at the sole expense of Atossa, all registerable rights in the Atossa Background IP, Atossa Data, Atossa Regulatory Information, Atossa Manufacturing Information, and Atossa Developments Records at all times. During the Term, Atossa shall have the exclusive right, but not the obligation, to prepare, file, prosecute, and maintain, at its sole cost and sole discretion, all registerable rights in the Atossa Foreground IP with a legal counsel of Atossa's sole choosing. Inventorship and authorship regarding Atossa Foreground IP shall be determined in accordance with U.S. patent and copyright laws. Atossa shall provide Besins a reasonable and meaningful opportunity to review and comment on such patent preparation, filing, prosecution and maintenance related to the Atossa Foreground IP and shall consider such input from Besins. Besins shall reasonably assist Atossa and Atossa's patent counsel, by consulting with Atossa's patent counsel regarding any Atossa Foreground IP and its preparation, filing, prosecution and maintenance; by providing technical and scientific advice; and by executing all papers and documents reasonably required to effectuate this Section 3.2(a).ii.

iii. Option to Continue to Prosecute and Maintain Patents included in Besins IP.

In the event Besins or its Affiliates or any of their respective successors in interest desires to cease prosecution and/or maintenance of any patents or patent applications ("Besins Discontinued Patent") within the Besins IP, it will promptly notify Atossa in writing of its intent to do so. If such Besins Discontinued Patent is within Besins Core IP, Besins shall permit Atossa to continue prosecution or maintenance of such Besins Discontinued Patent within Besins Core IP at Atossa's sole expense. If such Besins Discontinued Patent is within Besins Platform IP and if such Discontinued Patent is not licensed to a Third Party as of the date Besins sends notification in accordance with this subsection, Besins shall permit Atossa to continue prosecution or maintenance of such Besins Discontinued Patent within Besins Platform IP. If Atossa elects to continue prosecution or maintenance of any such Besins Discontinued Patent, Besins shall execute such documents and perform such acts at Atossa's sole expense as may be reasonably necessary to permit Atossa to prosecute and maintain such Besins Discontinued Patent.

iv. Option to Continue to Prosecute and Maintain patents included in Atossa Foreground IP

In the event Atossa or its Affiliates or any of their respective successors in interest desires to cease prosecution and/or maintenance of any patents or patent applications ("Atossa Discontinued Patent") within the Atossa Foreground IP, it will promptly notify Besins in writing of its intent to do so, and if such Discontinued Patent is not licensed to a Third Party as of the date Atossa sends notification in accordance with this subsection, Atossa shall permit Besins to continue prosecution or maintenance of such Atossa Discontinued Patent(s), at Besins' sole expense. If Besins elects to continue prosecution or maintenance of such Atossa Discontinued Patent(s), Atossa shall execute such documents and perform such acts at Besins' sole expense as may be reasonably necessary to permit Besins to prosecute and maintain such Atossa Discontinued Patent.

v. Notice of Patent Events.

Starting from the Effective Date of this Agreement, (i) Besins shall provide to Atossa semiannually a written update of any change in status of the patent portfolio in Besins Core IP and Besins Platform IP (Exhibits C and D), and (ii) Atossa shall provide to Besins semiannually a written update to the status of Atossa Foreground IP (Exhibit B).

vi. Trademarks.

Atossa, at its sole discretion, may elect to use Trademarks and trade dress licensed to it under Besins Core IP and Besins Platform IP, or to develop and use trademarks and trade dress of its own selection for use with Afimoxifene Gel.

(b) Enforcement and Defense of Intellectual Property.

i. <u>Notice</u>. If either Party becomes aware or reasonably believes that any Besins IP is being infringed in the Territory by a Third Party, or if a Third Party claims that any Besins IP is invalid or unenforceable in the Territory, it shall immediately disclose to the other Party in writing any such actual, threatened or suspected infringement of, or any action alleging invalidity or unenforceability of, any Besins IP.

ii. Infringement by Third Party.

- a. Besins shall have the first right, but not the obligation, to enforce and defend any Besins IP in the Territory at its sole cost, including, without limitation, to sue and collect damages for infringement, including past infringement or misappropriation, occurring prior to the Effective Date of this Agreement. Atossa shall have the first right, but not the obligation, to enforce any Atossa Background IP, Atossa Foreground IP, and Besins Discontinued Patents (collectively "Atossa IP"), including, without limitation, to sue and collect damages for infringement, including past infringement or misappropriation, and/or to defend against any Third Party claim of invalidity or unenforceability of any Atossa IP.
- b. During the Term, Besins shall continue to have the right, but not the obligation, to enforce and defend any Besins IP, including any Atossa Discontinued Patents (each, an "Action").
- (i) If the alleged infringing activities are outside the Field or in a Terminated Country, then the right is exclusive to Besins, at Besins' sole cost and expense, and Besins shall be entitled to retain any monetary recovery received by way of judgment or settlement or any other amounts collected relating to the Action or settlement or termination thereof. Atossa agrees to assist Besins, at Besins' expense, in any such Action, including by signing (or causing its Affiliates or personnel to sign) such documents as Besins shall reasonably request and, if necessary for Besins to bring or maintain such Action, joining in the Action as a party at Besins' sole expense.

- (ii) If the alleged infringing activities are in the Field in the Territory, then Atossa shall have the right, but not the obligation, to participate in such an Action at Atossa's sole expense. If Atossa elects not to join in the Action, Atossa nevertheless agrees to assist Besins, at Besins' expense, in any such Action, including by signing (or causing its Affiliates or personnel to sign) such documents as Besins shall reasonably request and, if necessary for Besins to bring or maintain such Action, joining in the Action as a party at Besins' sole expense, and Besins shall be entitled to retain any monetary recovery received by way of judgment or settlement or any other amounts collected relating to the Action or settlement or termination thereof. If Atossa elects to join the Action, then Besins and Atossa shall reasonably cooperate in such Action and the settlement or termination thereof, and each Party shall be entitled to share any monetary recovery received by way of judgment or settlement or any other amounts collected relating to the Action or settlement or termination thereof, to the extent such monetary recovery exceeds the Parties' legal fees and costs incurred in such enforcement or defensive Action.
- (iii) If the alleged infringing activities are in the Field in the Territory, and Besins notifies Atossa in writing of its intent not to take any measures against the alleged infringing activities, or fails to take any action within 45 days of a written request from Atossa that it do so, then Atossa shall have the right, but not the obligation, to do so at Atossa's sole expense, and Atossa will retain any monetary recovery received by way of judgment or settlement or any other amounts collected relating to the Action or settlement or termination thereof. Besins agrees to assist Atossa, at Atossa's expense, in any such Action, including by signing (or causing its Affiliates or personnel to sign) such documents as Atossa shall reasonably request and, if necessary for Atossa to bring or maintain such Action, joining in the Action as a party at Atossa's sole expense.

iii. Third Party Claims.

- a. *Notice*. Each Party shall immediately disclose to the other Party in writing any warning letter or other written notice of infringement or misappropriation received by a Party, or any action, suit or proceeding brought against a Party alleging infringement of a patent or misappropriation of intellectual property of any Third Party with regard to any aspect of the conduct by or for either Party pursuant to Development and Commercialization activities, or with respect to Afimoxifene Gel under this Agreement (each, a "Third Party Action").
- b. *Right to Defend*. Atossa shall have the first right, but not the obligation, to defend against any Third Party Action in the Territory, through counsel of its choosing reasonably satisfactory to Besins. Besins shall have the right, but not the obligation, to participate, at its own cost, in such an Action with counsel reasonably satisfactory to Atossa. If Atossa declines or fails to assert its intention to defend such claim within sixty (60) days of receipt/sending of notice thereof, then Besins shall have the right, but not the obligation, to defend such Third Party claim at its sole cost. If only one Party defends such a Third Party Action, the Party defending the Action shall have the sole and exclusive right to select counsel for such Third Party Action.

c. Consultation; Settlement. If both Besins and Atossa elect to participate in the Action, the Parties shall consult with one another on all material aspects of the defense of Third Party Actions. Each Party shall have a reasonable opportunity for meaningful participation in decision-making and formulation of defense strategy. The Parties shall reasonably cooperate with each other in all such Third Party Actions or proceedings, including in the settlement or termination thereof.

ARTICLE 4 Further Development, Regulatory Activities, and Commercialization

4.1 Responsibilities and Rights.

During the Term and except as otherwise expressly provided herein, Atossa, at its sole discretion, will have the exclusive right and be responsible for Developing and Commercializing Afimoxifene Gel in the Field in the Territory, filing applications for, and obtaining Regulatory Approvals for Afimoxifene Gel in the Field throughout the Territory. Atossa shall exclusively oversee, monitor, and coordinate all regulatory actions, communications and filings with and submissions to Regulatory Authorities, with respect to Afimoxifene Gel in the Field in the Territory, unless otherwise determined by Atossa. Atossa shall have the sole right, and shall be exclusively responsible, for corresponding and meeting with Regulatory Authorities with regard to Afimoxifene Gel in the Field in the Territory. Atossa shall have the exclusive right to file for, request, obtain and maintain any regulatory exclusivity rights conferred or granted by Regulatory Approval for Afimoxifene Gel and to conduct or prosecute any proceedings or actions to enforce such regulatory exclusivity rights. Atossa shall provide non-proprietary Data that it determines is reasonably necessary to obtain any such approvals, authorizations, permits or licenses. Upon sixty (60) business day prior written request by Besins, Atossa will provide Besins the opportunity to review any Atossa IND. The Parties agree that Atossa, at its sole discretion, will select dose concentrations for use of Afimoxifene Gel in the Territory.

Except as otherwise expressly provided herein, Atossa shall have the sole discretion to, determine and manage its own commercial strategy to market, promote and sell Afimoxifene Gel in the Field in the Territory.

4.2 Expansion of Field

Atossa may expand the Field to include an Additional Indication for which Besins or its Affiliates or Sublicensees has not already started Development or authorized a Third Party to start Development, upon sixty (60) business days' prior written notice to Besins and upon providing Besins with a Development Plan for the Additional Indication that shall supplement and become part of the Development Plan disclosed in **Exhibit E** (see below). The following Milestone Payments by Atossa will be due:

IND Milestone: \$5,000,000 for the exclusive right to review, access, and reference a Besins IND for each Additional Indication.

Phase 3 Milestone: \$20,000,000 when Atossa or its Affiliate or Sublicensee commences a Phase 3 clinical trial for each Additional Indication.

If Besins has started Development in an Additional Indication, Atossa may nevertheless request to expand the Field to include the Additional Indication, and Atossa may expand the Field to include the Additional Indication with Besins' written consent and payment of the above Milestone Payments.

Atossa or its Affiliate or Sublicensee shall not initiate any Clinical Study for an Additional Indication without first expanding the Field as described in this section.

4.3 **Development, Commercialization, Reversion of Rights.**

- (a) Development Plan. During the Term of the Agreement, the Parties shall meet in person, by video conference or telephonically, approximately every six months, to discuss the status of Development of Afimoxifene Gel under the Development Plan (the "Half-Yearly Meeting"). Atossa shall provide Besins with an initial Development Plan which shall cover an eighteen (18) month period commencing on the Effective Date and which shall become a part of this Agreement as Exhibit E. Atossa shall provide Besins with updated Development Plan at each Half-Yearly Meeting, such updated Development Plan shall become a part of Exhibit E and this Agreement. Thirty (30) days before any Half-Yearly Meeting Atossa shall provide to Besins a written half-yearly status report, which shall be ratified at the Half-Yearly Meeting, such ratification shall not be unreasonably withheld, denied or delayed. Atossa shall use Commercially Reasonable Efforts to follow the Development Plan. Upon request by Besins in writing, Atossa within ninety (90) days of receiving such request will provide Besins with copies of Atossa Data, Atossa Regulatory Information, Atossa Manufacturing Information, and Atossa Development Records on the use of Afimoxifene Gel in the Field in the Territory.
- (b) Atossa may, in its sole discretion, stop the Development and/or Commercialization of Afimoxifene Gel for an Indication in the Field in the Territory, as a whole or on a country-by-country basis, for any reason, upon sixty (60) business days' prior written notice to Besins. If Atossa elects to stop Developing or Commercializing Afimoxifene Gel for an Indication in the Field in the Territory, as a whole or on a country-by-country basis, the rights and license granted to Atossa under Article 2 shall terminate as to that Indication (a "Terminated Indication") and/or country (a "Terminated Country") and revert to Besins on the date of receipt by Besins of such written notice.

- (c) Notwithstanding anything to the contrary in this Agreement, Besins, in its sole discretion, may terminate the licenses granted under Sections 2.1(a) and (b) on an Indication-by-Indication or a country-by-country basis if (i) Atossa fails to Commercialize Afimoxifene Gel for such Indication (a "Terminated Indication") and/or in such country (a "Terminated Country") in the Territory within three (3) years of the First Commercial Sale of Afimoxifene Gel for use in such Indication anywhere in the Territory (which failure to launch was not caused by Besins' breach of its obligations hereunder or otherwise due to matters outside of Atossa's control) or (ii) the First Commercial Sale has not occurred five (5) years after the Effective Date (which failure to launch was not caused by Besins' breach of its obligations hereunder), and Besins notifies Atossa in writing that such licenses are being terminated, and such licenses shall revert to Besins on the date of receipt by Atossa of such written notice.
- (d) If Atossa fails to accomplish any aspect of the Development Plan for an Indication or in a country within the Territory within 6 months of date set forth in the Development Plan (which failure to accomplish was not caused by Besins' breach of its obligations hereunder and/or due to circumstances reasonably outside of Atossa's control), then Besins shall send Atossa a written notice of such defect and give Atossa a reasonable opportunity and time to cure such defect. In the event that Atossa fails to cure such defect, Besins in its sole discretion may terminate the licenses granted under Sections 2.1(a) and (b) as to that Indication (a "Terminated Indication") and/or country (a "Terminated Country"), provided that Besins notifies Atossa in writing that such licenses are being terminated. Such licenses shall revert to Besins on the date of receipt by Atossa of such written notice.
- (e) In the event that any licenses granted under Sections 2.1(a) and (b) revert to Besins under Section 4.3(b), (c), or (d), all rights and licenses granted by Atossa or its Affiliates to Atossa Affiliates, Atossa Sublicensees and any Third Party shall be terminated for any Terminated Indication(s) and/or in any Terminated Country(ies), and Atossa (for itself and its Affiliates) shall grant Besins and its Affiliates (i) irrevocable, perpetual, exclusive, royalty-free, fully paid, transferable license to continue the Development and/or Commercialization of Afimoxifene Gel for any Terminated Indication(s) and/or in any Terminated Country(ies), and (ii) irrevocable, perpetual, exclusive, royalty-free, fully paid license to rights existing as of the date of termination under Sections 4.3(b), (c), and (d) under Atossa Foreground IP, Atossa Know-How, Atossa Manufacturing Information, Atossa Data, Atossa Development Records, Atossa Regulatory Information, and Atossa Regulatory Approvals to Develop and Commercialize Afimoxifene Gel for any Terminated Indication(s) and/or in any Terminated Country(ies).

4.4 **Obligations of Besins.**

The Parties agree that an important purpose of this Agreement is to increase patient access to Afimoxifene Gel in the Field in the Territory. Besins agrees that Atossa shall have the exclusive right to make decisions in all matters regarding Development, Regulatory Approval and Commercialization of Afimoxifene Gel in the Field in the Territory.

Besins shall timely file all appropriate and necessary notices, documents, licenses and registrations with all Regulatory Authorities within the Territory (including, without limitation, Food and Drug Administration (FDA), European Medicines Agency (EMEA), The National Institute for Health and Care Excellence (NICE), granting Atossa the authorization to review, access, and reference Besins Regulatory Information solely with respect to Afimoxifene Gel in the Field in the Territory. Besins will furnish, at its sole cost, copies of IND 59,081 and IND 66,076 within ten (10) days of the Effective Date to permit Atossa to engage in Development and Commercialization activities and obtain Regulatory Approval under this Agreement. Besins will promptly provide Atossa with all Besins Regulatory Information, Besins Developmental Records, Besins Manufacturing Information, Besins Know-How, and such other information as necessary to accomplish Development and Commercialization of Afimoxifene Gel under this Agreement. Besins will promptly notify and disclose in writing any past, present and future violations of applicable laws and regulations, including regulatory compliance warning letters related to any Afimoxifene Gel. The obligation to disclose regulatory compliance violations regarding Afimoxifene Gel shall survive the expiration or termination of this Agreement.

Besins shall cooperate and use Commercially Reasonable Efforts to assist Atossa and/or any Sublicensee in procuring supply of the API for use in the Field in the Territory. In the event Atossa supplies the APIto Besins, Besins shall manufacture or have manufactured Afimoxifene Gel for Atossa at a cGMP quality that is at least the minimum acceptable to Regulatory Authorities in amounts sufficient to conduct at least Phase II clinical trials according to the Development Plan. Besins shall further cooperate and assist with technology transfer of all Manufacturing Information, packaging and labeling information to Atossa and/or Atossa Supplier or Sublicensee in order for Atossa to manufacture Afimoxifene Gel and perform Development and Commercialization activities under this Agreement and prepare all filings and submissions necessary to obtain Regulatory Approval of Afimoxifene Gel. Besins will provide Atossa any exclusivity or other regulatory exclusivity waivers as may be required by the applicable Regulatory Authority in order to use, make, have made manufacture, have manufactured, sell, offer for sale, import, have imported, export, have exported, distribute, or otherwise transfer Afimoxifene Gel in the Territory for use in the Field. Besins shall cooperate with Atossa to provide all other commercially reasonable assistance reasonably requested by Atossa, its Affiliates and Sublicensees in order to enable compliance with Atossa's obligations under Section 4.1.

ARTICLE 5 Financial Consideration

5.1 Intellectual Property Royalties to Besins.

- (a) Royalties.
- i. Know-How and Regulatory Information Royalties

As consideration for the licenses granted to Atossa and its Affiliates under this Agreement as of the Effective Date under Besins Know-How and Regulatory Information, beginning on the date of a First Commercial Sale of Afimoxifene Gel in the Field Atossa shall pay to Besins royalties equal to 8% (eight percent) of Net Sales of Afimoxifene Gel for use in the Field, on a country-by-country basis in the Territory.

ii. Patent Royalties

In addition to the Know-How and Regulatory Information Royalties, as consideration for the licenses granted to Atossa and its Affiliates under this Agreement under Besins patents, beginning on the date of a First Commercial Sale of Afimoxifene Gel in the Field, Atossa shall pay to Besins additional royalties equal to 1% (one percent) of Net Sales of Afimoxifene Gel for use in the Field in countries with a Valid Claim, on a country-by-country basis in the Territory, subject to the following adjustments:

If pursuant to Section 3.2.iii, Atossa elects to prosecute and maintain Besins Discontinued Patents, or if Besins elects not to enforce and defend any Besins Discontinued Patents in the Territory during the Term and Atossa elects to enforce and defend such Besins Discontinued Patents, royalty payments due to Besins under this Section 5.1(a)ii will be reduced by the costs, including attorney fees, incurred by Atossa of such prosecution, maintenance, enforcement and defense of such Besins Discontinued Patents. For clarity, adjustments under this Section 5.1(a)ii shall not exceed 1% (one percent) of Net Sales of Afimoxifene Gel for use in the Field in countries with a Valid Claim, on a country-by-country basis in the Territory.

- (b) <u>Payment</u>. All such royalty payments shall be paid semi-annually, within sixty (60) days after close of each six month period as provided below. Royalty payments shall be paid in US Dollars. With regards to sales in currencies other than US Dollars, conversion from local currency into US Dollars shall be the rate of exchange of the local currency to the US Dollar on the last day of the applicable 6-month period, as reported in The Wall Street Journal.
- (c) <u>Late Payments</u>. Late royalty payments shall incur interest at the rate equal to the one percent (1.0%) per month, calculated from the date such payments were originally due.
 - (d) Mode of Payment: Payments will be made by wire transfer, and shall be sent to an account specified in writing by Besins.
- (e) <u>Records</u>. For the purpose of computing royalties due to Besins hereunder, the year shall be divided into two parts ending on June 30 and December 31. Not later than sixty (60) days after each June 30 and December 31 in each calendar year during the Term, Atossa shall submit to Besins a full and detailed report of royalty payments due to Besins under the terms of this Agreement for the preceding half year (hereinafter the "**Half-Year Report**"), setting forth the Net Sales upon which such royalties are computed. If no royalty payments are due, a statement shall be sent to Besins stating such fact. Payment of the full amount of any royalty payments due to Besins for the half year represented in any Half Year Report shall accompany each such Half-Year Report. Atossa shall keep for a period of at least three (3) years after the date of entry, full, accurate and complete books and records consistent with sound business and accounting practices and in such form and in such detail as to enable the determination of the royalty payment amounts due to Besins pursuant to the terms of this Agreement.
- (f) Audit. Upon at least twenty (20) business days advance written notice and during Atossa's regular business hours, Besins' authorized representatives shall have the right to inspect the books of accounts and records of Atossa insofar as they relate to the sale of Afimoxifene Gel, or performance of Atossa's, its Affiliates, or any of their Sublicensees' obligations hereunder, in order to ascertain or verify the amount of royalty payments due to Besins hereunder and the accuracy of the information provided to Besins in the Half-Year Reports. Such audits shall be conducted during normal business hours and shall not unreasonably interfere with Atossa's conduct of its business. Each such audit shall be at Besins' expense unless a particular audit reveals an underpayment of greater than five percent (5%) of the amount that should have been paid to Besins for the period audited, in which case Atossa shall bear the reasonable expense of such audit. Besins will direct its representative to provide a copy of the audit report to Atossa. If any such audit reveals any inaccuracy in any statement, the necessary adjustments in such statements and the payments thereof will be promptly made and shall bear interest calculated at the late payment rate identified in Section 5.1(c) from the date the underpayment was made until paid. All audit rights shall survive the termination of this Agreement in full for a period of two (2) years (except with respect to audit rights as to any taxes or government surcharges which shall survive for the applicable statute of limitations, including any extensions thereof).

(g) <u>Challenge</u>. Besins shall have 60 days from receipt or acceptance by Besins of any Half-Year Report or corresponding royalty payment to challenge the validity or accuracy of such report or payment. Notwithstanding the foregoing, in the event any audit conducted pursuant to <u>Section 5.1</u> reveals any underpayment for a prior period, nothing in this <u>Section 5.1(g)</u> shall serve to limit any rights of Besins relating to such underpayment.

5.2 *Taxes*.

In the event that Atossa determines it is required by any Applicable Law to withhold any taxes from any payment made pursuant to this Agreement ("Withholding Taxes"), Atossa shall promptly provide written notice of the same to Besins and (i) withhold such Withholding Taxes from such payment; (ii) remit such Withholding Taxes to the appropriate governmental authority; (iii) pay to Besins the amount due as set forth in this Agreement, reduced by the amount of Withholding Taxes withheld and remitted to the appropriate governmental authority; and (iv) obtain and furnish to Besins a Withholding Tax receipt or other evidence of such remittance from the appropriate governmental authority. Notwithstanding the foregoing, if Besins is entitled under any applicable tax treaty to a reduction of rate of, or the elimination of, applicable Withholding Tax, it may deliver to Atossa or the appropriate governmental authority (with the assistance of Atossa to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve Atossa of its obligation to withhold tax, and Atossa shall apply the reduced rate of withholding, or dispense with withholding, as the case may be, *provided* that Atossa has received evidence of Besins' delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization).

5.3 Other Taxes.

Except as provided in Section 5.2, all taxes or duties in connection with payments made by Atossa shall be borne by Besins.

ARTICLE 6 Confidentiality and Publications

6.1 **Confidential Information.**

The Receiving Party will not use any Confidential Information of a Disclosing Party except for the purposes of performing its respective obligations under this Agreement. Each Receiving Party will maintain Confidential Information of the other Party in strict confidence and will use a standard of care, including procedures to prevent unauthorized disclosure or use of the other Party's Confidential Information and to prevent it from becoming disclosed or being accessed by unauthorized persons, that is at least as stringent as those used to protect Confidential Information of Receiving Party's own, but which shall in no event be less than a reasonable degree of care. The Receiving Party shall immediately advise the Disclosing Party of any unauthorized disclosure, loss, or use of Confidential Information of which Receiving Party becomes aware. Upon any termination or expiration of this Agreement, each Receiving Party agrees that all Confidential Information of the Disclosing Party, whether in written, graphic, or other tangible form, shall be returned to the Disclosing Party upon written request or destroyed at Disclosing Party's instruction, and a certificate of destruction duly signed by an authorized person on behalf of Receiving Party will be provided to the Disclosing Party. A single archival copy may be retained by the Receiving Party's legal department or counsel to meet Receiving Party's obligations under this Agreement and any requirements of Applicable Law. A deletion of electronic files containing or constituting Confidential Information shall be considered to be the destruction or return of such Confidential Information for purposes of this Agreement, *provided* that the deleted files must not be retrievable other than through extraordinary data salvage methods.

6.2 **Restrictions**.

Unless required by Applicable Law, the Receiving Party will not to disclose any Confidential Information of the Disclosing Party to any Third Party without the prior written consent of the Disclosing Party, except to its employees, agents, consultants, directors and officers that have a need to know such information to effectuate the purpose of this Agreement (each, a "Representative"); provided, that any such Representative shall be informed of the confidentiality provisions of this Agreement and shall be bound by a confidentiality agreement with the Receiving Party containing terms at least as restrictive as those contained in this Agreement and including post-employment confidentiality survival terms consistent with Section 6.1 of this Agreement (the "Representative Agreement"). The Receiving Party shall be liable for the actions or inactions of its Representatives that would constitute a breach of Article 6 of this Agreement were such Representatives a party hereto.

6.4 Exclusions.

Notwithstanding anything herein to the contrary, Confidential Information will not include information that: (i) is now or subsequently becomes generally available to the public through no act or omission of the Receiving Party or its Representatives; (ii) the Receiving Party can demonstrate in its contemporaneous written records to have had lawfully in its possession prior to disclosure to it by or on behalf of the Disclosing Party; (iii) is independently developed by the Receiving Party or individuals obligated to assign to the Receiving Party without use, directly or indirectly, of any Confidential Information of the Disclosing Party as evidenced by its contemporaneous written records; (iv) the Receiving Party lawfully obtains without obligation of confidentiality from a Third Party who has the right to disclose; or (v) is required by law or regulation to be disclosed, *provided* that the Receiving Party has provided prompt, advance written notice to the Disclosing Party so as to enable the Disclosing Party to seek a protective order or otherwise seek to prevent or limit disclosure of such Confidential Information, and the Receiving Party will reasonably cooperate in such efforts by the Disclosing Party; or (vi) pursuant to Section 6.9 of this Agreement; *provided* that if any disclosure must be made, the Receiving Party will only disclose Confidential Information to the extent it is required to be disclosed.

6.5 Third Party Information.

Further, for avoidance of doubt, Confidential Information of the Disclosing Party shall include Confidential Information received by the Disclosing Party from a Third Party. Prior to disclosure of such Third Party Confidential Information to the Receiving Party, the Disclosing Party shall determine that it has the right to make such disclosure, and will use its Commercially Reasonable Efforts to advise the Receiving Party that the disclosure includes Third Party Confidential Information.

6.6 Affiliates and Sublicensees.

This <u>Article 6</u> and the obligations herein shall apply to each Party and its officers, directors, employees, subcontractors, agents, Affiliates, Representatives, and Sublicensees. Each Receiving Party shall be responsible for causing such persons to comply with the obligations set forth in this <u>Article</u> 6.

6.7 **Term**.

A Receiving Party's obligations under this <u>Article 6</u> will continue for a period of seven (7) years following expiration or termination of this Agreement, or, with respect to Trade Secrets, for such longer period as may be provided by applicable law.

6.8 Relief.

Each Receiving Party agrees that any unauthorized disclosure, loss or use of Confidential Information may cause irreparable harm entitling the Disclosing Party to seek injunctive relief, in addition to any other remedies available to it at law or in equity.

6.9 Public Announcements.

Except as required by Applicable Law, the material terms of this Agreement will be considered Confidential Information of both Parties. Notwithstanding the foregoing sentence, (a) either Party may disclose such terms as are required, in the reasonable judgment of such Party and its counsel, to be disclosed in its publicly-filed financial statements or other public statements, pursuant to Applicable Laws, regulations and stock exchange rules (e.g., the rules of the U.S. Securities and Exchange Commission, NASDAQ, NYSE or any other stock exchange on which securities issued by either Party may be listed); and (b) either Party shall have the further right to disclose the material financial terms of this Agreement under a confidentiality obligation no less protective than those set forth in this Agreement, to any potential acquirer, licensee, lender, merger partner or potential providers of financing and their respective advisors. Neither Party shall make any other statement to the public regarding the execution and/or any other aspect of the subject matter of this Agreement without the prior review and consent of the other Party, except: (i) where a Party reasonably believes disclosure is required under Applicable Laws, (ii) the Parties shall have the right to announce the terms and existence of this Agreement in a press release at its execution, and (ii) either Party may use the text of a public statement previously approved by the other Party for disclosure. Attached as Exhibit F is the form of press release mutually agreed to by the Parties that either Party may release to announce the entry into this Agreement.

6.10 **Publications**.

Atossa shall have the exclusive right to publish the Atossa Data, Atossa Development Record, Atossa Background IP, and Atossa Foreground IP at its sole discretion in the Territory. For avoidance of doubt, Besins shall have no right of publication of Atossa Data, Atossa Development Records, Atossa Background IP, Atossa Foreground IP, Atossa Know-How, and Atossa Manufacturing Information under this Agreement without Atossa's prior written consent, and Atossa shall have no right of publication of Besins Core IP or Besins Platform IP without Besins' prior written consent, which shall not be unreasonably withheld, conditioned, or delayed.

ARTICLE 7 Representations and Warranties

7.1 Authority.

Each Party represents and warrants to the other Party that, as of the Effective Date:

(a) it is a corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction wherein it is organized;

- (b) it has the full power and authority under the laws of the state or country of its incorporation to enter into this Agreement and carry out its provisions, that the person executing this Agreement on its behalf has been authorized to do so by all requisite corporate action;
- (c) that its execution of and performance under this Agreement will not violate or breach any obligation or restriction (including, without limitation, any confidentiality or non-competition obligation or any exclusivity restriction) to which such Party is legally bound by contract, judicial order or otherwise; and no notice is required to or from any Third Party in connection with the transactions contemplated by this Agreement; and
- (d) upon full execution of this Agreement by the Parties hereto, this Agreement is a legal and valid obligation of the Party, binding upon the Party, and enforceable against the Party in accordance with the terms of this Agreement.

7.2 **Besins Representations and Warranties.**

As of the Effective Date and throughout the Term, Besins represents, warrants, and covenants that to the best of its knowledge:

- (a) its officers, directors, employees, subcontractors, agents, and Affiliates and any person who is performing or has performed under this Agreement is not under investigation by: (i) the FDA for debarment or disqualification action or is presently not debarred or disqualified pursuant to the Generic Drug Enforcement Act of 1992 (21 U.S.C. 301 et seq.); or (ii) any other Regulatory Authority for debarment or disqualification action or is not presently debarred or disqualified by any other Regulatory Authority;
- (b) it will provide a written certification, if requested by Atossa, to the representation and warranty of Section 7.2.a, and to promptly notify Atossa if any person who has performed activities under this Agreement is debarred or disqualified by the FDA or any other Regulatory Authority, but no later than ten (10) days after such disbarment or disqualification;
- (c) there is no action, suit, claim, investigation or proceeding pending or, to the best of its knowledge, threatened in writing against it that, if adversely decided, would be likely to adversely affect Besins' ability to enter into this Agreement or perform its obligations hereunder;
- (d) there is no action, claim, demand, suit, proceeding, arbitration, grievance, citation, summons or subpoena served upon it and it has not received any written notice of any ongoing inquiry, investigation or threat of any nature, civil, criminal, regulatory or otherwise, in law or in equity, relating to the activities contemplated and rights granted under this Agreement;
 - (e) it is not a party to any agreement that would prevent it from fulfilling its obligations under this Agreement;

- (f) there are no Encumbrances on Besins IP, Besins Manufacturing Information, INDs, Besins Regulatory Information, and Besins Development Record and it owns or upon their creation will own the rights and has or will have the right and power to grant the license rights granted to Atossa under this Agreement;
- (g) its performance under this Agreement does not and will not violate any Intellectual Property or proprietary rights of any Third Party, nor has any claim of such infringement been threatened or asserted; and
- (h) it has provided Atossa with all material information responsive to Atossa's diligence inquiries and such information in true and correct and does not contain any material omissions.

7.3 **FCPA.**

- (a) Each of the Parties warrants that it shall not make any payment, either directly or indirectly, of money or other assets, including but not limited to the compensation Parties derives from this Agreement, or provide any gifts, entertainment or other thing of value (hereinafter collectively referred as a "Payment") to government or political party officials, employees of state-owned entities, specifically including employees of state-owned medical/clinical facilities, officials of international organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing (collectively "Officials") where such Payment would constitute violation of any law, including the U.S. Foreign Corrupt Practices Act of 1977, 15 U.S.C. §§ 78dd-1, et seq. ("FCPA"). In addition, regardless of legality, the Parties shall make no Payment either directly or indirectly to Officials if such Payment is for the purpose of influencing decisions or actions with respect to the subject matter of this Agreement or any other aspect of its business.
- (b) Each Party warrants that it is familiar with the restrictions of all applicable anti-bribery/anti-corruption laws, including the FCPA, and that such Party shall provide appropriate training and education to anyone performing work on such Party's behalf under this Agreement on all such laws, including the FCPA.
- (c) Each Party shall report to the other in writing any suspected or actual violation of any anti-bribery/anti-corruption laws relating to this agreement immediately.

7.4 Atossa Representations and Warranties.

As of the Effective Date, Atossa represents, warrants, and agrees that to the best of its knowledge:

(a) its officers, directors, employees, subcontractors, agents, and Affiliates and any person who is performing or has performed under this Agreement is not under investigation by: (i) the FDA for debarment or disqualification action or is presently not debarred or disqualified pursuant to the Generic Drug Enforcement Act of 1992 (21 U.S.C. 301 et seq.); or (ii) any other Regulatory Authority for debarment or disqualification action or is not presently debarred or disqualified by any other Regulatory Authority;

- (b) it will provide a written certification, if requested by Besins, to the representation and warranty of Section 7.4.a, and to promptly notify Besins if any person who has performed activities under this Agreement is debarred or disqualified by the FDA or any other Regulatory Authority, but no later than ten (10) days after such disbarment or disqualification;
- (c) its officers, directors, employees, subcontractors, agents, and Affiliates shall comply with all Applicable Law, during the Term of and in the performance of this Agreement, and that Atossa's actions in establishing and performing this Agreement have been and will be consistent with ethical business practices and without the influence of any association with an Besins employee, officer or director that would amount to a conflict of interest;
- (d) there is no action, suit, claim, demand, or proceeding pending or, to the best of its knowledge, threatened in writing against it that, if adversely decided, would be likely to adversely affect Atossa's ability to enter into this Agreement or perform its obligations hereunder; and there is no action, claim, demand, suit, proceeding, arbitration, grievance, citation, summons or subpoena served upon it and it has not received any written notice of any ongoing inquiry, investigation or threat of any nature, civil, criminal, regulatory or otherwise, in law or in equity, relating to the activities contemplated and rights granted under this Agreement; and it is not a party to any agreement that would prevent it from fulfilling its obligations under this Agreement there are no Encumbrances on Atossa Know-How, Atossa Data, Atossa Background IP, Atossa Development Record, and Atossa Foreground IP, Atossa Manufacturing Information, and Atossa Regulatory Information and it owns or upon their creation will own the rights and has or will have the right and power to grant the license rights granted to Besins under this Agreement; and
- (e) its performance under this Agreement does not and will not violate any Intellectual Property or proprietary rights of any Third Party, nor has any claim of such infringement been threatened or asserted.

ARTICLE 8 Term and Termination

8.1 Expiration.

This Agreement will commence on the Effective Date and, unless otherwise earlier terminated pursuant to <u>Section 8.2</u>, will expire on a country-by-country basis, fifteen (15) years after the First Commercial Sale of Afimoxifene Gel in the Field in the applicable country in the Territory.

8.2 **Termination**.

- (a) Mutual Termination. The Parties may terminate this Agreement at any time upon their mutual written agreement.
- (b) Unilateral Termination. Besins may unilaterally terminate this Agreement in accordance with <u>Sections 4.3(c) and (d)</u>. Atossa may unilaterally terminate this Agreement in accordance with <u>Section 4.3(b)</u>.
- (c) <u>Breach</u>. Either Party, in its sole discretion, may terminate this Agreement if the other Party has materially breached this Agreement upon delivery of a sixty (60) days advance written notice to the other Party describing the breach and demanding its cure, and if the breaching Party has not cured the breach within the sixty (60) day period following receipt of such written notice of breach.
- (d) <u>Bankruptcy</u>. Either Party, in its sole discretion, may terminate this Agreement, effective immediately, upon written notice to the other Party upon: (i) the making by the other Party of an assignment for the benefit of creditors; (ii) the filing by the other Party of a voluntary petition in bankruptcy; (iii) the failure by the other Party to dismiss, within ninety (90) days of filing, a proceeding in bankruptcy against the other Party; (iv) appointment of a trustee or receiver (or similar official) of all or a substantial part of the property of the other Party under bankruptcy, insolvency or receivership laws; or (v) assumption of this Agreement by or on behalf of the other Party in any bankruptcy, insolvency or receivership proceeding.

8.3 Effect of Expiration or Termination.

- (a) In the event of expiration or termination of this Agreement, (i) Atossa shall remain the sole and exclusive owner of Atossa IP, Atossa Know-How, Atossa Regulatory Information, Atossa Development Record, and Atossa Manufacturing Information, subject to licenses granted under <u>Sections 2.2, 4.3(e)</u> and 8.3(c), and (ii) Besins shall remain the sole and exclusive owner of Besins IP, Besins Regulatory Information, Besins Manufacturing Information, and Besins Development Record, subject to the licensed rights under <u>Section 8.3(b)</u>.
- (b) <u>Non-exclusive License to Atossa</u>. Upon expiration of this entire Agreement under <u>Section 8.1</u> (but not termination under <u>Section 8.2</u>), and to the extent not terminated under <u>Section 4.3</u>, the exclusive royalty-bearing right and license granted to Atossa under <u>Section 2.1(a) and (b)</u> of this Agreement shall be converted to an irrevocable, perpetual, world-wide, royalty free, fully paid-up, non-exclusive, transferable right and license in the Field in the Territory.
- (c) Non-exclusive License to Besins. Upon expiration of this entire Agreement under Section 8.1 (but not termination under Section 8.2), and to the extent not terminated under Section 4.3, Atossa hereby grants to Besins and its Affiliates an irrevocable, perpetual, worldwide, non-exclusive right and license under Atossa Foreground IP to Develop and Commercialize Afimoxifene Gel in the Field in the Territory. As consideration for the license granted in this Section 8.3(c), Besins shall pay to Atossa royalties equal to 4% (four percent) of Besins Nets Sales in the Field in any country of the Territory with a Valid Claim, on a country-by-country basis. "Besins Nets Sales" means the gross revenue received by Besins, its Affiliates, their respective Sublicensees and Besins Third Party Resellers for the sale of Afimoxifene Gel to Third Parties other than Atossa and its Affiliates and Sublicensees (whether end-users, wholesalers or otherwise) in an arm's-length transaction, less the amount of the following deductions: (i) normal and customary trade, cash and quantity discounts actually given, credits, price adjustments or allowances for damaged products, returns or rejections of products, and allowance or rebates for retroactive price reductions; (ii) chargeback payments and rebates (or the equivalent thereof), if any, granted to group purchasing organizations, managed health care organizations or to federal, state/provincial, local and other governments, including their agencies, or to trade customers, wholesalers or other distributors; (iii) freight, shipping insurance and other transportation expenses directly related to shipments or deliveries of Afimoxifene Gel (if actually borne by Besins, its Affiliates or Sublicenses without reimbursement from any Third Party); (iv) sales taxes, value-added taxes, excise taxes, tariffs and duties of importation, and other taxes and any other similar government charges actually borne by Besins, its Affiliates or Sublicensees in connection with the sale or delivery of Afimoxifene Gel without reimbursement from any Third Party (but not including taxes assessed against the income derived from such sale); and (v) provisions for actual uncollectible accounts determined in accordance with U.S. generally accepted accounting principles, International Financial Reporting Standards, or such other accounting practices as Besins or its Affiliates or Sublicensees may, at their sole discretion, adopt, as consistently applied by Besins, its Affiliates, or Sublicensees (as applicable).

- (d) <u>Accrued Obligation</u>. Expiration or termination of this Agreement for any reason will not release either Party from any liability which has already accrued to the other Party or which is attributable to any event occurring or failing to occur during the Term of this Agreement prior to such expiration or termination.
- (e) <u>Survival</u>. As between the Parties, the rights and obligations of Atossa and Besins which by intent or meaning have validity beyond expiration or termination of this Agreement as set forth above, including, but not limited to, rights with respect to confidentiality, indemnification and liability limitations, shall survive the termination or expiration of this Agreement.
- (f) Termination of the entire Agreement under <u>Section 8.2</u> by either Party terminates all rights and licenses granted by such Party and its Affiliates to its Affiliates, Sublicensees and any Third Party. Termination of this Agreement by Atossa shall automatically terminate any and all sublicenses given by Atossa that grant to any Third Party any right under any Besins Intellectual Property.
- (g) <u>Remedies in Addition</u>. The termination provisions of this <u>Article 8</u> will not be exclusive, but rather will be in addition to any rights or remedies at law or in equity, or under this Agreement.

ARTICLE 9 Indemnification

9.1 Generally.

Each Party specifically reserves any common law right of indemnity and/or contribution which such Party may have against the other.

9.2 Indemnification of Atossa.

Besins shall indemnify, defend and hold Atossa, its officers, directors, employees, subcontractors, agents and Affiliates ("Atossa Indemnitees"), harmless from and against any and all liabilities, obligations, claims, demands, judgments, losses, deficiencies, costs, damages, expenses, fines, royalties, governmental penalties or punitive damages, interest, settlement amounts, awards, and judgments, (including reasonable, out-of-pocket attorneys', consultants' and other professional fees and disbursements) (collectively, "Losses") sustained by the Atossa Indemnitees arising from or out of any Third Party action, claim, demand, injunction, investigation, inquiry, proceeding, regulatory action, request or suit (collectively, "Claim(s)") related to:

- (a) Besins', its officers', directors', employees', subcontractors', agents' or Affiliates': (i) breach of any of its representations, warranties, agreements, covenants or obligations contained in or made pursuant to this Agreement; (ii) performance of Development under this Agreement by any of the Besins' Indemnitees; (iii) acts or omissions in performance by any of the Besins' Indemnitees of this Agreement; (iv) failure by any of the Besins' Indemnitees to comply with Applicable Law; (v) Development, manufacturing or other activities related to Afimoxifene Gel prior to the Effective Date and any commercialization of Afimoxifene Gel by any of the Besins' Indemnitees prior to the Effective Date, and (vi) negligence, gross negligence or willful misconduct of any of Besins' Indemnities, except in each case, to the extent such Losses arise from the gross negligence or willful misconduct of the Atossa; or a material breach of this Agreement by Atossa, which is not timely cured.
 - (b) Infringement, misappropriation or encroachment of any Third Party's personal, contractual or property rights by any of the Besins' Indemnitees.

9.3 **Indemnification of Besins**.

Atossa shall indemnify, defend and hold Besins, its officers, directors, employees, subcontractors, agents or Affiliates ("Besins Indemnitees") harmless from and against any and all Losses sustained by the Besins Indemnitees arising from or out of any Third Party Claims related to:

- (a) Atossa's, its officers', directors', employees', subcontractors', agents', or Affiliates': (i) breach of any of its representations, warranties, agreements, covenants or obligations contained in or made pursuant to this Agreement; (ii) performance of Development under this Agreement by any of the Atossa Indemnitees; (iii) acts or omissions in performance of this Agreement by any of the Atossa Indemnitees; (iv) failure by any of the Atossa Indemnitees to comply with Applicable Law; (v) Development, manufacturing or other activities related to Afimoxifene Gel following the Effective Date and commercialization of Afimoxifene Gel by any of the Atossa Indemnitees; and (vi) negligence, gross negligence or willful misconduct of any of the Atossa Indemnities, except in each case, to the extent such Losses arise from the gross negligence or willful misconduct of the Besins or a material breach of this Agreement by Besins, which is not timely cured; and
 - (b) Infringement, misappropriation or encroachment of any Third Party's personal, contractual or property rights by any of the Atossa's Indemnitees.

9.4 Notice; Settlement.

Each Party will promptly notify the other Party of any claim or liability for which indemnification is sought upon becoming aware thereof, *provided* that any delay or failure to give such notice will not relieve the indemnifying Party of its obligations hereunder except to the extent that the indemnifying Party is actually and materially prejudiced by such delay or failure. The Atossa Indemnitee(s) and Besins Indemnitees may respectively each, at their sole discretion and expense, participate and appear with the indemnifying Party in the defense of any Claim conducted by the indemnifying Party. The indemnifying Party may not settle any Claim, and no Party shall be responsible for or be bound by any settlement that imposes an obligation on it, without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed. Each indemnified Party shall cooperate with and provide to the other all information and assistance which the other Party may reasonably request in connection with any Claim entitling any Party to indemnification hereunder.

9.5 No Action.

If the indemnifying Party does not acknowledge its indemnification obligation hereunder with respect to a Claim and/or elects not to defend such Claim, the indemnified Party shall have the right, but not the obligation, to defend and settle such Claim until such time as the indemnifying Party acknowledges in writing its indemnification obligation hereunder with respect to such Claim and/or elects in writing to defend and settle such Claim in accordance with the indemnification provisions of this Article 9.

ARTICLE 10 Limitation of Liability and Insurance

10.1 Limitation of Liability.

Except for the Parties' obligations of Confidentiality set forth in <u>Article 6</u> and the Parties' obligations of Indemnification pursuant to <u>Article 10</u>, IN NO EVENT SHALL EITHER PARTY (INCLUDING THE BESINS INDEMNITEES OR ATOSSA INDEMNITEES, AS APPLICABLE) OR ANY OF ITS AFFILIATES BE LIABLE TO THE OTHER PARTY (INCLUDING THE BESINS INDEMNITEES OR ATOSSA INDEMNITEES, AS APPLICABLE) OR ANY OF ITS AFFILIATES FOR SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE ARISING OUT OF OR RELATING TO THIS AGREEMENT OR ANY BREACH THEREOF, EXCEPT TO THE EXTENT THAT ANY SUCH DAMAGES ARE PAYABLE TO A THIRD PARTY AS PART OF INDEMNIFICATION OF A THIRD PARTY CLAIM.

10.2 Insurance - Minimum Requirements.

- (a) Except as stated in Section 10.2.b below, from the Effective Date and for so long as Atossa is conducting the Development and Commercialization of Afimoxifene Gel hereunder, Atossa will, at its own cost, procure and continue in effect comprehensive general liability insurance that includes product liability coverage and coverage at the Commercialization stage for claims related to the Development and Commercialization of Afimoxifene Gel, with limits of not less than one million dollars (\$1,000,000.00) per occurrence for death or bodily injury and not less than three million dollars (\$3,000,000.00) in aggregate.
- (b) If Besins receives a license pursuant to Section 5.2 hereto, during the Term and for five years after expiration or termination of this Agreement, Besins will, at its own cost, procure and continue in effect comprehensive general liability insurance that includes product liability coverage at the Commercialization stage and coverage for claims related to the Development and Commercialization of Afimoxifene Gel, with limits of not less than one million dollars (\$1,000,000.00) per occurrence for death or bodily injury and not less than three million dollars (\$3,000,000.00) in aggregate.
- (c) <u>Notice</u>. Each Party shall provide evidence of such insurance upon written request by the other Party. Each Party shall notify the other Party in writing at least thirty (30) days prior to any cancellation, reduction in coverage or non-renewal of such policy.
- (d) <u>Non-limiting</u>. It is understood that this insurance shall not be construed as limiting either Party's indemnification obligations under this Agreement.

ARTICLE 11 Dispute Resolution

11.1 General.

Any occurrence of any breach, controversy, claim, default, or dispute relating to, arising out of or in any way connected to any provision or performance of this Agreement between the Parties ("Dispute") shall be discussed in good faith by the Parties in an effort to resolve the Dispute.

11.2 Officers.

If a Dispute cannot be resolved within thirty (30) days pursuant to discussions conducted in accordance with <u>Section 11.1</u>, either Party may, by written notice to the other Party, have such Dispute referred to the EVP of Research & Development for Besins and to the Chief Executive Officer at Atossa for resolution in which case the Parties shall cause the EVP of Research & Development for Besins and the Chief Executive Officer at Atossa to meet (in person or telephonically) during the following thirty (30) day period to discuss resolution of the Dispute.

11.3 *Venue*.

If a Dispute cannot be resolved in accordance with <u>Sections 11.1 and 11.2</u>, each of the Parties (i) agree that any legal suit, action or proceeding arising out of or relating to this Agreement and/or the transactions contemplated hereby will be instituted exclusively in the courts located in the State of Delaware (ii) waive any objection which it may have or hereafter to the venue of any such suit, action or proceeding, and (iii) irrevocably consents to the jurisdiction of the courts located in the State of Delaware, in any such suit, action or proceeding.

ARTICLE 12 Miscellaneous Provisions

12.1 Accounting Procedures.

All monetary amounts expressed in this Agreement are expressed in U.S. dollars. Each Party shall calculate all amounts hereunder and perform other accounting procedures required hereunder and applicable to it in accordance with the conventions, rules and procedures promulgated by the U.S. generally accepted accounting principles.

12.2 Affiliates.

Each Party shall have the right to have any of its obligations hereunder performed, or its rights hereunder exercised, by, any of its Affiliates with prior written notice to the other Party, and the performance of such obligations by any such Affiliate(s) shall be deemed to be performance by the Party; provided, that any such delegation by a Party to any of its Affiliates shall not relieve the delegating Party of any of its obligations under this Agreement and the delegating Party shall ensure the performance of its obligations under this Agreement in accordance with the terms and conditions of this Agreement and that any failure of any Affiliate performing any obligations of the delegating Party hereunder shall be deemed to be a failure by the delegating Party to perform such obligations. Each Party and any of its Affiliate performing any of the Party's obligations or receiving any benefits under this Agreement shall be responsible for all acts or omissions of the Party or its Affiliates' directors, officers, employees, contractors or consultants, and each Party and any such Affiliate shall be jointly and severally liable hereunder, and each Party shall have the right to enforce the terms of this Agreement against any such Affiliate of the other Party as if it were a Party.

12.3 Amendments.

No waiver, modification or amendment of any provision of this Agreement shall be valid or effective unless made in a writing referencing this Agreement and signed by a duly authorized officer of each Party.

12.4 Assignment; Binding.

Parties will have the right at its sole discretion to, assign, delegate or otherwise transfer (whether voluntarily, by operation of law or otherwise) this Agreement, or any of its rights or obligations hereunder with prior written consent of the other Party which shall not be unreasonably withheld, delayed or conditioned; *provided*, *however*, that either Party may assign this contract to an Affiliate or to an acquirer in connection with the merger or acquisition of the Party or all or substantially all the assets of the Party. Subject to the foregoing, this Agreement will be binding upon and will inure to the benefit of the Parties and their respective successors and permitted assigns. Any assignment by a Party in violation of this provision shall be void.

12.5 Compliance with Laws.

Each Party shall conduct, and shall use Commercially Reasonable Efforts to cause its Affiliates and subcontractors and its Affiliates' and subcontractors' employees, contractors and consultants to conduct, all activities contemplated under this Agreement in accordance with all Applicable Law. Each Party shall be liable for any action or inaction that would constitute a breach of this Agreement or breach of any Applicable Laws by its respective Affiliates, subcontractors and/or their respective employees or consultants, were such Affiliates, subcontractors and/or their respective employees or consultants a party hereto.

12.6 Construction.

This Agreement has been negotiated by the Parties and their respective counsel and will be interpreted fairly in accordance with its terms and without any strict construction in favor of or against either Party. Except where expressly stated otherwise in this Agreement, the following rules of interpretation apply to this Agreement: (a) "include," "includes" and "including" are not limiting and shall be deemed to be followed by "without limitation"; (b) definitions contained in this Agreement are applicable to the singular as well as the plural forms of such terms; (c) references to an agreement, statute or instrument mean such agreement, statute or instrument as from time to time amended, modified or supplemented; (d) captions and other headings to this Agreement are for convenience only, and shall have no force or effect in construing or interpreting any of the provisions of this Agreement or any other legal effect; (e) references to "Parties," "Article," "Section," "Exhibit" or "Schedule" refer to the Parties to, an Article or Section of, or any Exhibit or Schedule to, this Agreement unless otherwise indicated; (f) the word "will" shall be construed to have the same meaning and effect as the word "shall" and vice versa; and (g) the word "or" has, except where otherwise indicated, the inclusive meaning represented by the phrase "and/or".

12.7 Counterparts.

This Agreement may be executed (including, without limitation, by facsimile, electronic, or PDF signature) in one or more counterparts, each of which will be deemed an original instrument, and all of which will constitute one and the same agreement.

12.8 Force Majeure.

If the performance by a Party of any obligation under this Agreement, is prevented or impaired by an event of Force Majeure, the affected Party claiming an event of Force Majeure shall be excused from performance so long as such situation continues to prevent or impair performance, *provided* that the affected Party: promptly notifies the other Party in writing of the full particulars of the cause or event and the date of first occurrence thereof as soon as possible after the event; provides a date when full performance is expected to be resumed; and keeps the other Party informed of any further developments. The Party so affected shall use all Commercially Reasonable Efforts to remove the cause of non-performance, and each Party shall resume performance hereunder with the utmost dispatch when such cause is removed, unless this Agreement has been terminated according to its terms

12.9 Governing Law.

This Agreement will be governed by the laws of the State of Delaware applied to contracts made and to be wholly performed in the State of Washington.

12.10 Limited Rights and Obligations.

Each Party hereby acknowledges and agrees that the scope of the relationship between the Parties will be limited to the purposes and activities expressly set forth herein, and that the rights and obligations of the Parties with respect to each other will be limited to those expressly prescribed in this Agreement. Neither Party has any right, obligation or responsibility not specifically provided herein or authorized after the Effective Date by the mutual written agreement of the Parties, and nor will such right, obligation or responsibility will be implied by the terms and conditions of this Agreement or the conduct of the Parties hereunder.

12.11 *Notices*.

Any consent, notice or report required or permitted to be given or made under this Agreement by one of the Parties to the other shall be in writing and addressed to such other Party at its address indicated below, or to such other address as the addressee Party shall have last furnished in writing to the addressor Party, and shall be considered effective and/or received: (i) upon the date of receipt by the addressee Party if hand delivered; (ii) if sent via electronic mail, upon the date a personalized electronic mail confirmation or acknowledgment of receipt is sent; (iii) upon the date delivered by the U.S. postal service via registered or certified mail, or by reputable courier service, in each case, as indicated with a written confirmation or acknowledgement of receipt.

If to Atossa: Steven Quay, CEO and President

ATOSSA GENETICS, INC. 2345 Eastlake Ave E, Suite 201 Seattle, WA, 98102. U.S.A.

If to Besins: Leslie Grunfeld, CEO

Besins Healthcare Holding Ltd

AGildo Pastor Center 7 rue du Gabian, 98000 Monaco

lgrunfeld@besins-healthcare.com

With a copy to:

François Brault, Head of Legal Affairs: fbrault@besins-healthcare.com

12.12 Relationship of the Parties.

The Parties acknowledge that this Agreement does not create a fiduciary relationship between them, and that the Parties are independent contractors of the other, and that nothing in this Agreement is to make either Party an agent, legal representative, subsidiary, joint venturer, partner, employee or servant of the other for any purpose whatsoever. Neither Party nor its agents have any authority of any kind to bind the other Party in any respect whatsoever, and the relationship of the Parties is, and at all times will continue to be, that of independent contractors.

12.13 Severability.

In the event that any provisions of this Agreement are determined for any reason to be invalid or unenforceable by a court of competent jurisdiction, the remainder of the Agreement will remain in full force and effect without that provision. In such event, the Parties will in good faith negotiate a substitute clause for any provision declared invalid or unenforceable, which will most nearly approximate the intent of the Parties.

12.14 Use of Names.

Except as provided in <u>Section 6.10</u>, neither Party will use the name, symbol or logo of the other Party without the other Party's prior written consent except as required by law. Each Party shall keep the other Party informed about any of its activities that involve using the other Party's name.

12.15 Waiver.

The waiver of or failure to enforce by one Party any breach of any term, covenant, or condition contained in this Agreement will not be construed or deemed to be a waiver of any subsequent or similar breach of the same or any other term, covenant, representation, warranty, or condition; nor will any delay or omission on the part of either Party to exercise or avail itself of any right or remedy that it has or may have hereunder operate as a waiver of any right or remedy.

12.16 Solicitation of Employees.

The Parties agree that during the term of this Agreement and during the twelve (12) month period commencing on the date that such term expires or is terminated, they shall not for any reason, either directly or indirectly, on their own behalf or in the service of or on behalf of others, solicit, recruit or attempt to persuade any person to terminate such person's employment with the other Party, whether or not such person is a full-time employee or whether or not such employment is pursuant to a written agreement or is at-will; *provided* that either Party may hire an employee of the other in the event such employee answers a general advertisement for employment (not targeted to employees of the other Party) or seeks employment without any prior solicitation by the hiring Party.

SIGNATURES FOLLOW ON THE NEXT PAGE

IN WITNESS WHEREOF, the undersigned, intending to be legally bound, have duly executed this Agreement as of the date first above written.

BESINS HEALTHCARE. ATOSSA GENETICS INC.

By: /s/ Leslie Grunfeld By: /s/ Steven C. Quay

[signature] [signature]

Name: <u>Leslie Grunfeld</u> Name: Steven C. Quay

Title: CEO Title: CEO

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Exhibit A – Atossa Background IP Claiming Afimoxifene Gel.

None

Exhibit B – Atossa Foreground IP

None. To be completed after execution of Agreement when IP is developed.

Exhibit C – Besins Core IP

A	Hyperplasia & Benign Breast Disease			
	Country	Application #	Registration #	Status
1	Australia	2005227072	2005227072	Granted/Registered
2	Austria	05716433.7	1748770	Granted/Registered
3	Belgium	05716433.7	1748770	Granted/Registered
4	Canada	2559748	2559748	Granted/Registered
5	China	200580009172.4	1946387	Granted/Registered
6	Denmark	05716433.7	1748770	Granted/Registered
7	European Patent Application	05716433.7	1748770	Granted/Registered
8	Finland	05716433.7	1748770	Granted/Registered
9	France	05716433.7	1748770	Granted/Registered
10	Germany	05716433.7	1748770	Granted/Registered
11	Greece	05716433.7	1748770	Granted/Registered
12	Hong Kong	07102275.5	HK1096595	Granted/Registered
13	Ireland	05716433.7	1748770	Granted/Registered
14	Italy	05716433.7	1748770	Granted/Registered
15	Japan	2007-504377	5072588	Granted/Registered
16	Luxembourg	05716433.7	1748770	Granted/Registered
17	Mexico	PA/A/2006/010914	262962	Granted/Registered
18	Monaco	05716433.7	1748770	Granted/Registered
19	Netherlands	05716433.7	1748770	Granted/Registered
20	New Zealand	549817	549817	Granted/Registered
21	Norway	20064609		Application Pending
22	PCT Application	PCT/EP2005/003286		Case Closed
23	Poland	05716433.7	1748770	Granted/Registered
24	Portugal	05716433.7	1748770	Granted/Registered
25	Russian Federation	2006137280	2357726	Granted/Registered
26	Spain	05716433.7	1748770	Granted/Registered
27	Sweden	05716433.7	1748770	Granted/Registered
28	Switzerland	05716433.7	1748770	Granted/Registered
29	Turkey	05716433.7	1748770	Granted/Registered
30	United Kingdom	05716433.7	1748770	Granted/Registered
31	USA	10/805528	7507769	Granted/Registered
32	USA	12/397487	8048927	Granted/Registered

В	Breast Cancer			
	Country	Application #	Registration #	Status
1	Australia	2003294973	2003294973	Granted/Registered
2	Canada	2519980	2519980	Granted/Registered
3	European Patent Application	03785958.4	1608353	Granted/Registered
4	European Patent Application	08103007.4	1952810	Granted/Registered
5	European Patent Application	08103014.0	1941871	Granted/Registered
6	France	03785958.4	1608353	Granted/Registered
7	France	08103007.4	1952810	Granted/Registered
8	France	08103014.0	1941871	Granted/Registered
9	Germany	03785958.4	1608353	Granted/Registered
10	Germany	08103007.4	1952810	Granted/Registered
11	Germany	08103014.0	1941871	Granted/Registered
12	Hong Kong	06107310.2	HK1086193	Granted/Registered
13	Hong Kong	08113909.5	HK1119950	Granted/Registered
14	Ireland	03785958.4	1608353	Granted/Registered
15	Ireland	08103007.4	1952810	Granted/Registered
16	Ireland	08103014.0	1941871	Granted/Registered
17	Israel	170807	170807	Granted/Registered
18	Italy	03785958.4	1608353	Granted/Registered
19	Italy	08103007.4	1952810	Granted/Registered
20	Italy	08103014.0	1941871	Granted/Registered
21	Japan	2004-570040	5490346	Granted/Registered
22	Luxembourg	03785958.4	1608353	Granted/Registered
23	Luxembourg	08103007.4	1952810	Granted/Registered
24	Luxembourg	08103014.0	1941871	Granted/Registered
25	Mexico	PA/a/2005/010597	279293	Granted/Registered
26	Netherlands	03785958.4	1608353	Granted/Registered
27	Netherlands	08103007.4	1952810	Granted/Registered
28	Netherlands	08103014.0	1941871	Granted/Registered
29	New Zealand	542499	542499	Granted/Registered
30	Norway	20054526	333805	Granted/Registered
31	PCT Application	PCT/EP2003/015029		Case Closed
32	Spain	03785958.4	1608353	Granted/Registered
33	Spain	08103007.4	1952810	Granted/Registered
34	Spain	08103014.0	1941871	Granted/Registered
35	Switzerland	03785958.4	1608353	Granted/Registered
36	Switzerland	08103007.4	1952810	Granted/Registered
37	Switzerland	08103014.0	1941871	Granted/Registered
38	United Kingdom	03785958.4	1608353	Granted/Registered
39	United Kingdom	08103007.4	1952810	Granted/Registered
40	United Kingdom	08103014.0	1941871	Granted/Registered
41	USA	12/353890	8475814	Granted/Registered

С	Mastalgia			
	Country	Application #	Registration #	Status
1	Australia	2003303033	2003303033	Granted/Registered
2	Austria	03813146.2	1572178	Granted/Registered
3	Belgium	03813146.2	1572178	Granted/Registered
4	Bulgaria	03813146.2	1572178	Granted/Registered
5	Canada	2509660	2509660	Granted/Registered
6	Cyprus	03813146.2	1572178	Granted/Registered
7	Czech Republic	03813146.2	1572178	Granted/Registered
8	Denmark	03813146.2	1572178	Granted/Registered
9	Estonia	03813146.2	1572178	Granted/Registered
10	European Patent Application	03813146.2	1572178	Granted/Registered
11	Finland	03813146.2	1572178	Granted/Registered
12	France	03813146.2	1572178	Granted/Registered
13	Germany	03813146.2	1572178	Granted/Registered
14	Greece	03813146.2	1572178	Granted/Registered
15	Hong Kong	05108810.6	HK1075403	Granted/Registered
16	Hungary	03813146.2	1572178	Granted/Registered
17	Ireland	03813146.2	1572178	Granted/Registered
18	Italy	03813146.2	1572178	Granted/Registered
19	Japan	2004-560487	4938237	Granted/Registered
20	Luxembourg	03813146.2	1572178	Granted/Registered
21	Mexico	PA/A/2005/006526	256654	Granted/Registered
22	Monaco	03813146.2	1572178	Granted/Registered
23	Netherlands	03813146.2	1572178	Granted/Registered
24	New Zealand	540494	540494	Granted/Registered
25	PCT Application	PCT/EP2003/015028		Case Closed
26	Portugal	03813146.2	1572178	Granted/Registered
27	Romania	03813146.2	1572178	Granted/Registered
28	Slovakia	03813146.2	1572178	Granted/Registered
29	Slovenia	03813146.2	1572178	Granted/Registered
30	Spain	03813146.2	1572178	Granted/Registered
31	Sweden	03813146.2	1572178	Granted/Registered
32	Switzerland	03813146.2	1572178	Granted/Registered
33	Turkey	03813146.2	1572178	Granted/Registered
34	United Kingdom	03813146.2	1572178	Granted/Registered
35	USA	10/734640	7786172	Granted/Registered

D	Breast Density			
	Country	Application #	Registration #	Status
1	European Patent Application	03813147.0	1572171	Granted/Registered
2	European Patent Application	08103001.7		Application Pending
3	European Patent Application	09000839.2		Application Pending
4	France	03813147.0	1572171	Granted/Registered
5	Germany	03813147.0	1572171	Granted/Registered
6	Hong Kong	05110203.7	HK1077512	Granted/Registered
7	Hong Kong	09100877.9		Application Pending
8	Hong Kong	09109465.8		Application Pending
9	Japan	2004-560488	4684655	Granted/Registered
10	Japan	2010-279107		Case Closed
11	PCT Application	PCT/EP2003/015030		Case Closed
12	United Kingdom	03813147.0	1572171	Granted/Registered
13	USA	10/734644	7485623	Granted/Registered

E	Gynomastia]		
	Country	Application #	Registration #	Status
1	Australia	2004298349	2004298349	Granted/Registered
2	Austria	04803913.5	1694319	Granted/Registered
3	Belgium	04803913.5	1694319	Granted/Registered
4	Canada	2549824	2549824	Granted/Registered
5	Czech Republic	04803913.5	1694319	Granted/Registered
6	Denmark	04803913.5	1694319	Granted/Registered
7	European Patent Application	04803913.5	1694319	Granted/Registered
8	Finland	04803913.5	1694319	Granted/Registered
9	France	04803913.5	1694319	Granted/Registered
10	Germany	04803913.5	1694319	Granted/Registered
11	Greece	04803913.5	1694319	Granted/Registered
12	Hong Kong	07100340.0	HK1094768	Granted/Registered
13	Hungary	04803913.5	1694319	Granted/Registered
14	Ireland	04803913.5	1694319	Granted/Registered
15	Italy	04803913.5	1694319	Granted/Registered
16	Japan	2006-543519	5069469	Granted/Registered
17	Luxembourg	04803913.5	1694319	Granted/Registered
18	Mexico	PA/A/2006/006834	262238	Granted/Registered
19	Monaco	04803913.5	1694319	Granted/Registered
20	Netherlands	04803913.5	1694319	Granted/Registered
21	New Zealand	547744	547744	Granted/Registered
22	Norway	20062904		Application Pending
23	PCT Application	PCT/EP2004/014295		Case Closed
24	Poland	04803913.5	1694319	Granted/Registered
25	Portugal	04803913.5	1694319	Granted/Registered
26	Romania	04803913.5	1694319	Granted/Registered
27	South Africa	2006/05579	2006/05579	Granted/Registered
28	Spain	04803913.5	1694319	Granted/Registered
29	Sweden	04803913.5	1694319	Granted/Registered
30	Switzerland	04803913.5	1694319	Granted/Registered
31	Turkey	04803913.5	1694319	Granted/Registered
32	United Kingdom	04803913.5	1694319	Granted/Registered
33	USA	11/009390	7968532	Granted/Registered

F	Breast Scarring			
	Country	Application #	Registration #	Status
1	Australia	2004246812	2004246812	Granted/Registered
2	Austria	04740032.0	1631275	Granted/Registered
3	Belgium	04740032.0	1631275	Granted/Registered
4	Canada	2528431	2528431	Granted/Registered
5	Denmark	04740032.0	1631275	Granted/Registered
6	European Patent Application	04740032.0	1631275	Granted/Registered
7	France	04740032.0	1631275	Granted/Registered
8	Germany	04740032.0	1631275	Granted/Registered
9	Hong Kong	06103609.1	HK1082203	Granted/Registered
10	Ireland	04740032.0	1631275	Granted/Registered
11	Italy	04740032.0	1631275	Granted/Registered
12	Japan	2006-515986	4682129	Granted/Registered
13	Luxembourg	04740032.0	1631275	Granted/Registered
14	Mexico	PA/A/2005/013435	257512	Granted/Registered
15	Monaco	04740032.0	1631275	Granted/Registered
16	Netherlands	04740032.0	1631275	Granted/Registered
17	New Zealand	544031	544031	Granted/Registered
18	PCT Application	PCT/EP2004/006583		Case Closed
19	Portugal	04740032.0	1631275	Granted/Registered
20	Spain	04740032.0	1631275	Granted/Registered
21	Sweden	04740032.0	1631275	Granted/Registered
22	Switzerland	04740032.0	1631275	Granted/Registered
23	Turkey	04740032.0	1631275	Granted/Registered
24	United Kingdom	04740032.0	1631275	Granted/Registered
25	USA	10/858399	7767717*	Granted/Registered

^{*} As this specific patent (US7,767,717) is co-owned by Besins with Northwestern University, U.S.A., the Parties agree that, should Atossa exercise its option under Section 4.2 to expand the Field to the Additional Indication "other breast diseases" to include equivalent licenses under US7,767,717, then Besins shall make its best efforts to ensure that Atossa be authorized to obtain licensing rights from the co-owner and to assist Atossa in negotiating exclusivity with the co-owner.

Exhibit D – Besins Platform IP

Α	Formulations			
	Country	Application #	Registration #	Status
1	Australia	2003294973	2003294973	Granted/Registered
2	Canada	2519980	2519980	Granted/Registered
3	European Patent Application	08103014.0	1941871	Granted/Registered
4	France	08103014.0	1941871	Granted/Registered
5	Germany	08103014.0	1941871	Granted/Registered
6	Hong Kong	08113909.5	HK1119950	Granted/Registered
7	Ireland	08103014.0	1941871	Granted/Registered
8	Italy	08103014.0	1941871	Granted/Registered
9	Japan	2004-570040	5490346	Granted/Registered
10	Luxembourg	08103014.0	1941871	Granted/Registered
11	Mexico	PA/a/2005/010597	279293	Granted/Registered
12	Netherlands	08103014.0	1941871	Granted/Registered
13	New Zealand	542499	542499	Granted/Registered
14	Norway	20054526	333805	Granted/Registered
15	PCT Application	PCT/EP2003/015029		Case Closed
16	Spain	08103014.0	1941871	Granted/Registered
17	Switzerland	08103014.0	1941871	Granted/Registered
18	United Kingdom	08103014.0	1941871	Granted/Registered
19	USA	10/734638	7704516	Granted/Registered

В	E/Z Isomers]		
	Country	Application #	Registration #	Status
1	Argentina	P050101125		Application Pending
2	Australia	2005227073	2005227073	Granted/Registered
3	Austria	05735277.5	1727532	Granted/Registered
4	Belgium	05735277.5	1727532	Granted/Registered
5	Bulgaria	05735277.5	1727532	Granted/Registered
6	Canada	2557806	2557806	Granted/Registered
7	China	200580009171.X	101080222	Granted/Registered
8	Czech Republic	05735277.5	1727532	Granted/Registered
9	Denmark	05735277.5	1727532	Granted/Registered
10	European Patent Application	05735277.5	1727532	Granted/Registered
11	European Patent Application	09175781.5	2147670	Granted/Registered
12	European Patent Application	10180921.8	2269599	Granted/Registered
13	Finland	05735277.5	1727532	Granted/Registered
14	France	05735277.5	1727532	Granted/Registered
15	France	09175781.5	2147670	Granted/Registered
16	France	10180921.8	2269599	Granted/Registered
17	Germany	05735277.5	1727532	Granted/Registered
18	Germany	09175781.5	2147670	Granted/Registered
19	Germany	10180921.8	2269599	Granted/Registered
20	Greece	05735277.5	1727532	Granted/Registered
21	Hong Kong	07104159.2	HK1098674	Granted/Registered
22	Hong Kong	10106178.9		Application Pending
23	Hungary	05735277.5	1727532	Granted/Registered
24	India	2453/KOLNP/2006	251984	Granted/Registered
25	Ireland	05735277.5	1727532	Granted/Registered
26	Ireland	09175781.5	2147670	Granted/Registered
27	Ireland	10180921.8	2269599	Granted/Registered
28	Israel	177778	177778	Granted/Registered
29	Israel	215897		Granted/Registered
30	Italy	05735277.5	1727532	Granted/Registered
31	Italy	09175781.5	2147670	Granted/Registered
32	Italy	10180921.8	2269599	Granted/Registered
33	Japan	2007-504378	5489407	Granted/Registered
34	Luxembourg	05735277.5	1727532	Granted/Registered
35	Luxembourg	09175781.5	2147670	Granted/Registered
36	Luxembourg	10180921.8	2269599	Granted/Registered
37	Mexico	PA/A/2006/010928	279114	Granted/Registered
38	Monaco Netherlands	05735277.5	1727532 1727532	Granted/Registered Granted/Registered
39 40	Netherlands	05735277.5 09175781.5	2147670	Granted/Registered Granted/Registered
41	Netherlands	10180921.8	2269599	Granted/Registered
42	New Zealand	549664	549664	Granted/Registered
43	Norway	20064765	343004	Application Pending
44	PCT Application	PCT/EP2005/003455		Case Closed
45	Poland	05735277.5	1727532	Granted/Registered
46	Portugal	05735277.5	1727532	Granted/Registered
47	Romania	05735277.5	1727532	Granted/Registered
48	Russian Federation	2006137282	2389483	Granted/Registered
49	South Africa	2006/07291	2006/07291	Granted/Registered
50	Spain	05735277.5	1727532	Granted/Registered
51	Spain	09175781.5	2147670	Granted/Registered
52	Spain	10180921.8	2269599	Granted/Registered
53	Sweden	05735277.5	1727532	Granted/Registered
54	Switzerland	05735277.5	1727532	Granted/Registered
55	Switzerland	09175781.5	2147670	Granted/Registered
56	Switzerland	10180921.8	2269599	Granted/Registered
57	Taiwan	094108588	I401078	Granted/Registered
58	Turkey	05735277.5	1727532	Granted/Registered
59	United Kingdom	05735277.5	1727532	Granted/Registered
60	United Kingdom	09175781.5	2147670	Granted/Registered
61	United Kingdom	10180921.8	2269599	Granted/Registered
62	USA	10/805530		Application Pending
		1	1	1 11

С	4X Formulation]		
	Country	Application #	Registration #	Status
1	Algeria	070224	5132	Granted/Registered
2	Armenia	200700834	011295	Granted/Registered
3	Australia	2005293712	2005293712	Granted/Registered
4	Austria	05803579.1	1799201	Granted/Registered
5	Azerbaijan	200700834	011295	Granted/Registered
6	Belarus	200700834	011295	Granted/Registered
7	Belgium	05803579.1	1799201	Granted/Registered
8	Brazil	PI0518139-9		Application Pending
9	Bulgaria	05803579.1	1799201	Granted/Registered
10	Canada	2582174	2582174	Granted/Registered
11	China	200580035353.4	101065120	Granted/Registered
12	Colombia	07036907	1377	Granted/Registered
13	Croatia	05803579.1	1799201	Granted/Registered
14	Cyprus	05803579.1	1799201	Granted/Registered
15	Czech Republic	05803579.1	1799201	Granted/Registered
16 17	Denmark Ecuador	05803579.1 SP-07-7396	1799201	Granted/Registered Application Pending
18	Estonia	05803579.1	1799201	Granted/Registered
19	Eurasian Patent	200700834	011295	Granted/Registered
20	Eurasian Patent European Patent Application	05803579.1	1799201	Granted/Registered Granted/Registered
21	Finland	05803579.1	1799201	Granted/Registered
22	France	05803579.1	1799201	Granted/Registered
23	Georgia	9987/01	P 2010 4889 B	Granted/Registered
24	Germany	05803579.1	1799201	Granted/Registered
25	Greece	05803579.1	1799201	Granted/Registered
26	Hong Kong	07111311.2	HK1103027	Granted/Registered
27	Hungary	05803579.1	1799201	Granted/Registered
28	Iceland	05803579.1	1799201	Granted/Registered
29	India	1133/KOLNP/2007		Application Pending
30	Ireland	05803579.1	1799201	Granted/Registered
31	Israel	182298	182298	Granted/Registered
	Italy	05803579.1	1799201	Granted/Registered
32	Japan	2007-536126	5047800	Granted/Registered
33	Kazakhstan	200700834	011295	Granted/Registered
34	Kyrgyzstan	200700834	011295	Granted/Registered
35	Latvia	05803579.1	1799201	Granted/Registered
36	Lithuania	05803579.1	1799201	Granted/Registered
37	Luxembourg	05803579.1	1799201	Granted/Registered
38	Macedonia	05803579.1	1799201	Granted/Registered
39	Mexico	MX/A/2007/004371	263103	Granted/Registered
40	Moldova	200700834	011295	Granted/Registered
41	Monaco	05803579.1	1799201	Granted/Registered
42	Morocco	PV29815	28927	Granted/Registered
43	Netherlands	05803579.1	1799201	Granted/Registered
44	New Zealand	554206	554206	Granted/Registered
45	Nigeria	186/07	NG/C/2007/909	Granted/Registered
46	Norway	20072463	12700	Application Pending
47	OAPI DCT Application	1200700149	13780	Granted/Registered
48	PCT Application Poland	PCT/EP2005/011654 05803579.1	1700201	Case Closed Granted/Registered
50	Portugal	05803579.1	1799201 1799201	Granted/Registered Granted/Registered
51	Romania	05803579.1	1799201	Granted/Registered Granted/Registered
52	Russian Federation	200700834	011295	Granted/Registered Granted/Registered
53	Serbia Serbia	05803579.1	1799201	Granted/Registered Granted/Registered
54	Singapore	2007027055	131527	Granted/Registered
55	Slovakia	05803579.1	1799201	Granted/Registered
56	Slovenia	05803579.1	1799201	Granted/Registered
57	South Africa	2007/03016	2007/03016	Granted/Registered
58	South Korea	10-2007-7008384	10-1294947	Granted/Registered
59	Spain	05803579.1	1799201	Granted/Registered
60	Sweden	05803579.1	1799201	Granted/Registered
61	Switzerland	05803579.1	1799201	Granted/Registered
62	Tajikistan	200700834	011295	Granted/Registered
63	Tunisia	SN07.139		Application Pending
64	Turkey	05803579.1	1799201	Granted/Registered
65	Turkmenistan	200700834	011295	Granted/Registered
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66	Ukraine	a200705192	87335	Granted/Registered
67	United Kingdom	05803579.1	1799201	Granted/Registered
68	USA	60/638359		Case Closed
69	USA	11/249122		Application Pending
70	Uzbekistan	IAP20070138	IAP03817	Granted/Registered
71	Viet Nam	1-2007-00777		Application Pending

D	Dermis			
	Country	Application #	Registration #	Status
1	Australia	2010311523	2010311523	Granted/Registered
2	Brazil	BR112012010083.1		Application Pending
3	Canada	2778689		Application Pending
4	China	201080059696.5		Application Pending
5	European Patent Application	10768983.8		Application Pending
6	Hong Kong	12112691.3		Application Pending
7	India	1111/MUMNP/2012		Application Pending
8	Israel	219236		Application Pending
9	Japan	2012-535814	5727494	Granted/Registered
10	PCT Application	PCT/EP2010/066283		Case Closed
11	Russian Federation	2012121708		Application Pending
12	South Africa	2012/02855	2012/02855	Granted/Registered
13	USA	12/912310		Application Pending

E	Stable Gel			
	Country	Application #	Registration #	Status
1	European Patent Application	04712591.9	1594545	Granted/Registered
2	France	0302083	2851470	Granted/Registered
3	France	04712591.9	1594545	Granted/Registered
4	Germany	04712591.9	1594545	Granted/Registered
5	Hong Kong	06105598.9	HK1084590	Granted/Registered
6	Japan	2006-502159	4925103	Granted/Registered
7	PCT Application	PCT/FR2004/000393		Case Closed
8	United Kingdom	04712591.9	1594545	Granted/Registered
9	USA	10/436380	7611727	Granted/Registered

Exhibit E – Afimoxifene Gel Development Plan

	Exhibit E Atossa Genetics 4	4-OHT 18 Month Development Plan
ID	Task Name	2nd Quarter 3rd Quarter 4th Quarter 1st Quarter 2nd Quarter 3rd Quarter Apr. May Jun Jul Aug Sep Oct Nov Dec Jan Feb Mar Apr May Jun Jul Aug Sep
1	Atossa/Besins Deal Complete	5/15
2	Establish Atossa IND with FDA	
3	Establish 4-OHT API Supply	
4	Montrouge to Manufacture Gel Drug Product	
5	Initial IRB Approvals and Site Contracts	
6	First Patient Enrolled	*

Exhibit F - Press Release



Atossa Genetics Acquires

Rights to Clinical Stage Proprietary Afimoxifene Gel for

Potential Treatment of Hyperplasia of the Breast

Sixteen Completed Clinical Studies Provide Support for Phase 2 Program

SEATTLE, May ___, **2015** -- Atossa Genetics, Inc. (NASDAQ: ATOS) today announced that it has acquired from Besins Healthcare an exclusive license to Besins' patented gel formulation of 4-Hydroxytamoxifen, or Afimoxifene Gel, which Atossa intends to develop for the potential treatment of hyperplasia of the breast.

Steven C. Quay, M.D., Ph.D., President and CEO, commented, "Atossa's strategy is to improve breast health through a three step approach: providing our patented medical devices to collect nipple aspirate fluid, testing the fluid for the presence of hyperplasia, and then treating the hyperplasia with the local delivery of a proprietary pharmaceutical. Obtaining the rights to Besins' Afimoxifene Gel represents considerable advancement towards developing the crucial third step of this process."

"Besins has developed substantial pre-clinical and clinical data that we intend to utilize to advance the Afimoxifene Gel, to be used in conjunction with our devices and laboratory tests. We intend to secure a manufacturing source for a clinical supply of Afimoxifene Gel and to advance the clinical development into a Phase II clinical trial using our proprietary devices, laboratory tests and the Afimoxifene Gel. Besins is a recognized leader in the development and commercialization of hormone therapies and we believe their proprietary Afimoxifene Gel may, in conjunction with our breast aspirator devices and cytology tests, be developed as a local treatment for hyperplasia," commented Dr. Quay.

Leslie Grunfeld, CEO of Besins Healthcare, commented, "Besins Healthcare has spent a number of years developing and advancing Afimoxifene Gel. We are pleased that Atossa, who are focused on breast health, will continue the development for the treatment of local hyperplasia in conjunction with their existing technology. Various studies have shown that Afimoxifene Gel could be effective for other related indications and we are hopeful to be able to develop these in the future".

Key terms of the license are:

- · Exclusive world-wide rights to develop and commercialize Afimoxifene Gel for the potential treatment and prevention of hyperplasia of the breast
- · No upfront or milestone payments to Besins.
- · Royalty of 8% 9% of net sales for the first 15 years of commercialization.
- · Atossa has the non-exclusive right to also develop Afimoxifene Gel for breast cancer and other breast diseases (subject to milestone payments for these additional indications).
- · Atossa obtains access to Besins' pre-clinical and clinical studies and data for the treatment of breast pain with Afimoxifene Gel, which include animal, toxicity, and clinical trials with 144 patients. Results from additional 82 patients have been published from pre-surgical studies in invasive breast cancer and ductal carcinoma in situ, or DCIS, conducted respectively in France and the United States. Across all indications, over 450 patients have been treated with Afimoxifene Gel.
- · Besins has the right of first refusal to commercialize the Afimoxifene Gel on a country-by-country basis in countries where they have a marketing presence.

"One of our four key objectives for 2015 is to commence a clinical study using a local therapy to treat a serious breast health condition. This new exclusive license arrangement with Besins significantly advances this key objective," continued Dr. Quay.

About Atossa Genetics

Atossa Genetics Inc. is focused on improving breast health through the development of laboratory services, medical devices and therapeutics. The laboratory services are being developed by its subsidiary, The National Reference Laboratory for Breast Health, Inc. The laboratory services and the Company's medical devices are being developed so they can be used as companions to therapeutics to treat various breast health conditions. For more information, please visit www.atossagenetics.com.

About Besins Healthcare

Besins Healthcare is a privately owned pharmaceutical company specialized in the development and worldwide diffusion of innovative drugs for the well-being of men and women throughout their lives. Over the last 30 years Besins Healthcare has established a strong and reputable name in the production of innovative drugs for the treatment of gynecological, fertility and obstetrical conditions as well as androgen deficiency.

Besins has become a renowned player in the area of hormonal therapies. Innovative products from Besins Healthcare are distributed in more than 90 countries around the world through subsidiary companies as well as a network of business partners.

About Afimoxifene and Afimoxifene Gel

Afimoxifene (4-hydroxytamoxifen), an active metabolite of tamoxifen, is an anti-estrogen with an affinity for estrogen receptor that is up to 50 fold higher compared with that of tamoxifen. Afimoxifene Gel is a proprietary transdermal gel formulation of Afimoxifene protected by 10 patent families. It can be dispensed from a convenient metered-dose container. Besins has completed a comprehensive preclinical pharmacology and toxicology package on Afimoxifene Gel and its manufacturing CMC package is expected to be sufficient to support Atossa's Phase 3 Program. A total of 16 Phase-1 and -2 studies have been conducted in a variety of indications in the United States, United Kingdom, France, Poland, and Czech Republic. These studies enrolled over 450 patients total, and results were published in leading medical journals such as the Journal of Clinical Oncology (*J Clin Oncol 2005;23:2980-87*), Clinical Cancer Research (*Clin Cancer Res 2014;20:3672-82*), and Breast Cancer Research and Treatment (*Breast Cancer Res Treat 2007;106:389-97*). Systemic distribution of topically delivered Afimoxifene Gel was minimal with little difference in adverse events between Afimoxifene Gel and placebo. The occurrence of hot flushes or night sweats, vaginal dryness, vaginal bleeding, and nipple discharge were similar between the treatment arm and placebo.

Forward-Looking Statements

Forward-looking statements in this press release are subject to risks and uncertainties that may cause actual results to differ materially from the anticipated or estimated future results, including the risks and uncertainties associated with actions by the FDA, the outcome or timing of regulatory approvals needed by Atossa to sell its products, responses to regulatory matters, Atossa's ability to achieve its objectives, continue to manufacture and sell its products, recalls of products, the safety and efficacy of Atossa's products and services, performance of distributors, whether Atossa can launch and commercialize in the United States and foreign markets the additional tests, devices and therapeutics in its pipeline in a timely and cost effective manner, and other risks detailed from time to time in Atossa's filings with the Securities and Exchange Commission, including without limitation its periodic reports on Form 10-K and 10-Q, each as amended and supplemented from time to time. Atossa does not undertake any obligation to update any forward looking statement.

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