

---

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 8-K/A  
(Amendment No. 1)

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 23, 2013**

**OCULUS INNOVATIVE SCIENCES, INC.**  
(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-33216**  
(Commission  
File Number)

**68-0423298**  
(IRS Employer  
Identification No.)

**1129 N. McDowell Blvd, Petaluma, CA**  
(Address of principal executive offices)

**94954**  
(Zip Code)

**(707) 283-0550**  
(Registrant's telephone number, including area code)

**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 (see General Instruction A.2. below):

- £ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- £ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- £ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- £ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
- 
-

## Explanatory Note

Oculus Innovative Sciences, Inc. (the "Company") is filing this Amendment No. 1 (the "Amendment") to its Current Report on Form 8-K originally filed with the Securities and Exchange Commission on June 7, 2013 (the "Original Report") solely to provide certain omitted portions of the License and Supply Agreement by and between the Company and Ruthigen, Inc., dated May 23, 2013, which was filed as Exhibit 10.1 to the Original Report. Following correspondence with the Securities and Exchange Commission, Exhibit 10.1 is being re-filed to alter portions of Exhibit 10.1 as to which confidential treatment is being requested pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

Except as described above, no other changes have been made to the Original Report. This Amendment speaks as of the original filing date of the Original Report, and the disclosures contained herein have not been updated to reflect events, results or developments that have occurred after filing of the Original Report or to modify or update those disclosures affected by subsequent events. Accordingly, this Amendment should be read in conjunction with the Original Report and the Company's other filings made with the Securities and Exchange Commission.

### Item 9.01 Financial Statements and Exhibits.

- 10.1\* License and Supply Agreement by and between Oculus Innovative Sciences, Inc. and Ruthigen, Inc., dated May 23, 2013
- 10.2 Shared Services Agreement by and between Oculus Innovative Sciences, Inc. and Ruthigen, Inc., dated May 23, 2013 (included as Exhibit 10.2 to the Company's Current Report on Form 8-K, filed June 7, 2013, and incorporated herein by reference).
- 10.3 Offer of Employment Letter between Oculus Innovative Sciences, Inc. and Sameer Harish, effective as of February 1, 2013 (included as Exhibit 10.1 to the Company's Current Report on Form 8-K, filed February 4, 2013, and incorporated herein by reference).
- 10.4 Amendment to Offer of Employment Letter between Oculus Innovative Sciences, Inc. and Sameer Harish, dated May 23, 2013 (included as Exhibit 10.4 to the Company's Current Report on Form 8-K, filed June 7, 2013, and incorporated herein by reference).
- 99.1 Press release issued by Oculus Innovative Sciences, Inc. dated June 6, 2013 (included as Exhibit 99.1 to the Company's Current Report on Form 8-K, filed June 7, 2013, and incorporated herein by reference).

\* Confidential treatment has been requested with respect to certain portions of this exhibit. These portions have been omitted from this report and submitted separately to the Securities and Exchange Commission pursuant to a Confidential Treatment Request under Rule 24b-2 of the Exchange Act.

## 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.

Oculus Innovative Sciences, Inc.  
(Registrant)

Date: September 24, 2013

/s/ Robert Miller  
Name: Robert Miller  
Title: Chief Financial Officer

## License and Supply Agreement

THIS LICENSE AND SUPPLY AGREEMENT (the "Agreement") is executed as of the 23 day of May, 2013, shall become effective upon the closing of an IPO (as hereinafter defined) (the "Effective Date"), and is entered into by and between Ruthigen, Inc., a Nevada corporation ("Ruthigen") and Oculus Innovative Sciences, Inc., a Delaware corporation (hereinafter referred to as "Oculus"). Oculus and Ruthigen are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

WHEREAS, Oculus has developed proprietary technology and know-how which is incorporated into a broad range of products that it manufactures, through its methods of manufacturing (including the Oculus Method of Manufacturing defined below) and commercializes.

WHEREAS, Oculus has also developed proprietary technology and know-how relating to the manufacture of a unique and proprietary chemical formulation.

WHEREAS, Ruthigen is interested in developing and commercializing products utilizing the proprietary technology and know-how generally for invasive applications and obtaining from Oculus certain rights and licenses therefor, on the terms and subject to the conditions hereinafter set forth.

WHEREAS, on the terms and subject to the conditions hereinafter set forth, Oculus is willing to grant such rights and licenses to Ruthigen, while retaining the right to develop and commercialize products utilizing the proprietary technology and know-how generally for topical applications, as well as to continue to develop and commercialize products using the Oculus Method of Manufacturing.

WHEREAS, Oculus and Ruthigen will each seek input from the other Party into certain of its respective policies, strategies and goals for the development and commercialization of certain of its respective products, and maximization of commercialization and differentiation of such products, all as set forth herein.

NOW, THEREFORE, in consideration of the foregoing recitals and the mutual covenants and agreements contained herein, the Parties hereto, intending to be legally bound, do hereby agree as follows:

### Article I Definitions

The following terms, when capitalized, shall have the following meanings (such meanings to be equally applicable to both the singular and plural forms of the terms defined), when used in this Agreement.

"Affiliate" means, with respect to a Party, any person, corporation, firm, joint venture, or other entity which, directly or indirectly, by itself or through one or more intermediaries, controls, is controlled by, or is under common control with such Party, but only for so long as such control exists. As used in this definition, the term "control" means the possession of the power to direct or cause the direction of the management and policies of an entity, whether through the ownership of the outstanding voting securities or by contract or otherwise. For purposes of this Agreement and notwithstanding any control relationship between the Parties, neither Party shall be deemed an Affiliate of the other Party.

“Agreement” means this License and Supply Agreement.

“Audit Disagreement” shall have the meaning set forth in Section 8.7(b).

“Business Day” means a day which is not a Saturday, a Sunday or other day on which banks are required or authorized by law to be closed in San Francisco, California.

“CFR” means the US Code of Federal Regulations.

“Change in Control” means, with respect to a Party, the occurrence of any of the following events:

(a) The acquisition of a Party by another person or entity by means of any transaction or series of related transactions (including, without limitation, any reorganization, merger or consolidation), or the sale of all or substantially all of the assets of the Party, unless, in connection with such acquisition or sale of assets, the Party’s shareholders as constituted immediately prior to such acquisition or sale shall, immediately after such acquisition or sale (by virtue of securities issued as consideration for the Party’s acquisition or sale or otherwise) have “beneficial ownership” (as defined in Rule 13d-3 under the Securities and Exchange Act of 1934, as amended (the “Exchange Act”)) of securities of the surviving or acquiring person or entity representing more than fifty percent (50%) of the combined voting power of the surviving or acquiring person or entity ordinarily having the right to vote at elections of directors;

(b) The shareholders of the Party approve a plan of complete liquidation of the Party; or

(c) Any transaction or series of related transactions to which a Party is a party in which ownership of in excess of fifty percent (50%) of the Party’s outstanding voting power is transferred and as a result of which the holders of the voting power of the outstanding capital stock of such Party immediately prior to such transaction, own less than fifty percent (50%) of the then outstanding capital shares of securities or equity entitled to vote generally in the election of the directors (or other managing authority) of such Party immediately following such transaction.

For purposes of this definition, the term “person” shall have the same meaning as when used in sections 13(d) and 14(d) of the Exchange Act but shall exclude (1) a trustee or other fiduciary holding securities under an employee benefit plan maintained by the Party or an Affiliate and (2) a corporation owned directly or indirectly by the shareholders of the Party in substantially the same proportions as their ownership of the stock.

Notwithstanding the foregoing, the term Change in Control shall not include a transaction the primary purpose of which is (a) to change the state or country of the Party’s incorporation, (b) to form a holding company that will be owned in substantially the same proportions by the persons who held the Party’s securities immediately before such transaction; (c) to engage in an equity financing transaction; or (d) to make an initial public offering of the Party’s stock.

“Clinical Development” means the conduct of studies of the Product in humans in the Field to assess the dosing, safety and/or efficacy of the Product, including but not limited to Phase 1 Clinical Trials, Phase 2 Clinical Trials and Phase 3 Clinical Trials, or as required by the applicable Regulatory Authority.

“Commercialization” and “Commercialize” shall refer to all activities undertaken relating to the use, pre-marketing, marketing, sale, offer for sale import for sale and distribution of the Product, through Ruthigen, its Affiliates and their sublicensees, distributors and resellers.

“Commercially Reasonable Efforts” means the carrying out of obligations or tasks in a sustained manner using good faith and diligent efforts, which efforts shall be consistent with the exercise of prudent scientific and business judgment.

“Confidential Information” shall have the meaning set forth in Section 10.1.

“Consolidated Group” shall be determined in accordance with U.S. GAAP, consistently applied.

“Control” or “Controlled” means the right to grant a license or sublicense of patent rights, know-how, information, or other intangible rights as provided for herein without violating the terms of any agreement or other arrangement with any Third Party.

“Cost of Goods” means (i) with respect to any unit of Product, Oculus’ direct out of pocket product production cost per unit of Product, including raw materials, packaging components (if any), and direct internal and outside labor allocable to such unit of Product in accordance with Oculus’s observed accounting procedures and using GAAP, consistently applied, for all products Manufactured in the facility where the Product is manufactured; and (ii) with respect to any unit of Manufacturing Equipment, Oculus’ direct out of pocket product acquisition cost per unit of Manufacturing Equipment, including raw materials, packaging, components, and direct outside labor for assembly allocable to such unit of Manufacturing Equipment in accordance with Oculus’s observed accounting procedures and using GAAP, consistently applied, for all Manufacturing Equipment manufactured in the facility where the Manufacturing Equipment is assembled.

“Development” and “Develop” means to develop a product, including conducting non-clinical and clinical research and development activities such as toxicology, pharmacology and other discovery efforts, test method development and stability testing, process development, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, clinical studies (including pre- and post-approval studies), regulatory affairs, pharmacovigilance and clinical study regulatory activities, including, with respect to Ruthigen, all activities relating to the Pre-clinical Development, clinical development and post-sale assessment and monitoring of Products in the Field in the Territory.

“Development and Commercialization Plan” means the plan attached as Schedule 3 hereto, which sets forth the expected Development and Commercialization to be conducted by Ruthigen that will set forth the regulatory approvals to be sought, the timelines for such approvals and timelines for Ruthigen’s Commercialization of Product in the Field in the Territory.

“Drug Approval Application” means an application for Regulatory Approval which is required before commercial sale or use of the Product as a drug in the Territory.

“FAC” means free available chlorine.

“FDA” means the U.S. Food and Drug Administration, or any successor health regulatory authority.

“FD&C Act” means the United States Federal Food, Drug, and Cosmetic Act, as amended, and the rules and regulations promulgated thereunder.

“Field” means all (1) Invasive uses in humans, other than (i) dermatologic, and (ii) unless and until Ruthigen exercises the OOS Option, the Indications in humans; and (2) if and when Ruthigen exercises the OOS Option, the Indications in humans.

“First Commercial Sale” means with respect to a Product, the date Ruthigen or an Affiliate or sublicensee of Ruthigen first sells commercially, pursuant to Regulatory Approval, the Product in the Territory.

“GAAP” means United States generally accepted accounting principles consistently applied.

“Good Manufacturing Practice” and cGMP mean the then-current standards for the manufacture of FDA regulated products, as set forth in, or required by the FDA pursuant to, the FD&C Act and applicable regulations promulgated thereunder, as amended from time to time, and such standards of good manufacturing practice as are set forth in or required by the applicable laws and regulations of countries other than the United States in which Products are intended to be sold, and their respective Regulatory Authorities.

“IND” means an Investigational New Drug application filed with the FDA pursuant to 21 CFR 312.1 *et seq.*

“Indications” means the ophthalmic, sinusitis and otic indications.

“Invasive” means penetrating the endothelial and epithelial barrier, whether by (i) incision; (ii) injection; or (iii) through use of a medical device; and in each case of (i), (ii) and (iii), to deliver the Substance to reach the internal body cavity, tissue and/or organs. For the avoidance of doubt, “Invasive” does *not* include: (A) non-sterile device oral care products in liquid or gel formulation using the Oculus Method of Manufacturing and having [ ]\* with greater than [ ]\*% degradation in [ ]\* concentration over a [ ]\* ([ ]\*) month shelf life pursuant to product release studies, (B) sterile or non-sterile products for use with endotracheal tube disorders using the Oculus Method of Manufacturing and having [ ]\* with greater than [ ]\*% degradation in [ ]\* concentration over a [ ]\* ([ ]\*) month shelf life pursuant to product release studies, (C) non-sterile device products targeted for use with vacuum assisted closure products using the Oculus Method of Manufacturing and having [ ]\* with greater than [ ]\*% degradation in [ ]\* concentration over a [ ]\* ([ ]\*) month shelf life pursuant to product release studies; (D) sterile or non-sterile device products for cleaning catheters using the Oculus Method of Manufacturing and having [ ]\* with greater than [ ]\*% degradation in [ ]\* concentration over a [ ]\*([ ]\*) month shelf life pursuant to product release studies, (E) Urinary Tract Infection Products, (F) non-sterile wound care products using the Oculus Method of Manufacturing and having [ ]\* with greater than [ ]\*% degradation in [ ]\* concentration over a [ ]\* ([ ]\*) month shelf life pursuant to product release studies in the United States, (G) sterile wound care products using the Oculus Method of Manufacturing and having [ ]\* with greater than [ ]\*% degradation in [ ]\* concentration over a [ ]\* ([ ]\*) month shelf life pursuant to product release studies in the European Union, and (H) any services employing any of the products described in (A) – (G) of this section.

“IPO” means a public offering of the common stock of Ruthigen, whether consummated through the declaration of effectiveness of an S-1 registration statement in the United States or similar documentation under the laws of another jurisdiction, by reverse merger or any other mechanism for gaining access to the public markets of any country.

“Know-how” means: (i) techniques, data and information relating to the Substance or the Product in connection with the Field, including, but not limited to, inventions, discoveries, practices, methods, manufacturing processes, raw materials, sketches, supplier and vendor information, standard operating processes, knowledge, know-how, skill, trade secrets, experience, test data and results (including pharmacological, toxicological, preclinical, and clinical test data); data, records, and information derived from preclinical development or clinical development, regulatory submissions, adverse reactions, analytical and quality control data, marketing, pricing, distribution, cost, sales and manufacturing data or descriptions, and market research and competitive data, and (ii) compound, compositions of matter and assays and protocols relating to the Substance or the Product in connection with the Field.

\* Confidential material redacted and separately filed with the Commission.

“Losses” shall have the meaning set forth in Section 13.1.

“Manufacture” or “Manufacturing” means all activities directed to making, producing, validating, manufacturing, processing, filling, finishing, packaging, labeling, sterilizing, quality assurance testing and release, shipping or storage of a product, including all activities involved in the production of Products to be supplied by Oculus to Ruthigen hereunder, and all activities involved in the production of Products by or for Ruthigen, including the preparation, testing, packaging, storage and labeling of such Products and the handling, storage and disposal of any residues or wastes generated thereby.

“Manufacturing Equipment” means the equipment used or manufactured by Oculus to Manufacture the Substance and Product for Ruthigen using the Ruthigen Method of Manufacturing.

“NDA” means a new drug application filed with the FDA to obtain marketing approval for the Product in the Field in the Territory.

“Net Sales” means the gross amounts invoiced or paid to Ruthigen and its Affiliates and sublicensees by distributors or customers for Products in the Territory, in each case, less the following items, as allocable to the Product (if not previously deducted from the amount invoiced) if taken in compliance with GAAP: (i) trade, quantity or cash discounts, credits or allowances; (ii) credits or allowances reserved for returns, rejections, bad debt or unpaid invoices, rebates or recalls; (iii) allowances for chargebacks and other amounts paid on sale or dispensing of such Product; (iv) rebates or other price reductions provided to any Governmental Authority in respect of any state or federal Medicare, Medicaid or similar programs; (v) freight, shipping and insurance charges if stated on and included in the applicable invoice; (vi) tariffs, duties and excise, sales, value-added or other taxes (other than taxes based on income) charged for the sale, distribution, delivery or use of the Product if stated on and included on the applicable invoice; and (vii) credits, chargebacks and prime vendor rebates, fees, reimbursements, and similar payments actually granted or given to wholesalers, distributors, buying groups, health care insurance carriers, pharmacy benefit management companies, health maintenance organizations, other similar institutions or health care organizations or other customers that are in excess of amounts previously reserved as allowances at the time of sale.

For the avoidance of doubt, Net Sales do not include intercompany transfers of Products between Ruthigen and its Affiliates for resale, but does include amounts invoiced or received by Ruthigen from Affiliates or sublicensee for use of a Product by its Affiliate or sublicensee, and amounts invoiced or received by Ruthigen and its Affiliates from distributors, and amounts invoiced or received by Affiliates and sublicensees from Third Parties on the resale of such Product, to the extent not duplicative.

If a Product is sold in combination with another product, component or service (such as in a kit), which other product, component or service if sold alone would not be subject to a royalty payment hereunder, then Net Sales from such combination sales, for purposes of calculating the amounts due under Section 8.1 shall be calculated by multiplying the gross selling price of the combination product by the fraction  $(A/(A+B))$ , where A is the gross selling price, during the royalty period in question, of the Product sold separately, and B is the gross selling price, during the royalty period in question, of the other products, components or services, sold separately. If the other products, components or services are not sold separately during that royalty period, then the Net Sales on the combination product or service shall be as reasonably allocated by Ruthigen between such Product and such other product, component or service and as agreed upon by Oculus in writing, which agreement shall not be unreasonably withheld or delayed. In calculating Net Sales on such combination products or services, Ruthigen shall not sell or offer for sale a product or service for use with a Product at a price that is higher than the fair market value for such product or process while concurrently selling or offering for sale the accompanying Product at a price that is lower than the fair market value for such Product for purposes of reducing the royalty owed to oculus based upon the sale of such Product.

“Oculus Know-how” means Know-how within the Control of Oculus as of the Effective Date or which comes within the Control of Oculus during the term of this Agreement and relates to the Manufacturing of the Substance and/or the Product in the Field in the Territory. Oculus Know-how includes all Know-how necessary or useful in support of the operation, repair and maintenance of the Manufacturing Equipment. Oculus Know-how includes Joint Technology, if any.

“Oculus Method of Manufacturing” means any method of Manufacturing certain liquids incorporating chlorine that generates a product that, except as otherwise expressly provided in this Agreement, (i) has [ ]\* at the time of commercial release, and (ii) with or without chemical additives has a decrease of greater than [ ]\*% in [ ]\* concentration over a [ ]\* ([ ]\*) month shelf life pursuant to product release studies; or such greater concentration of [ ]\* and/or such other change in concentration over a [ ]\* ([ ]\*) month shelf life as the Parties agree pursuant to Section 2.4(c). The Oculus Method of Manufacturing does not include the Ruthigen Method of Manufacturing.

“Oculus Patents” means any Patents in the Territory owned by Oculus or its Affiliates as of the Effective Date or which come within the ownership or Control of Oculus. Oculus Patents include Joint Patents, if any.

“Oculus Product” means (i) any sterile drug product or service directed for the Indications, unless and until Ruthigen exercises the OOS Option, the Indications, and (ii) any non-sterile drug or medical device product or service which is (a) produced using the Ruthigen Method of Manufacturing and/or the Oculus Method of manufacturing, and (b) will not be used, sold or offered for sale in the Field. All Oculus Products must be sold in the hydrogel form, except that Oculus Products directed for the indication of acne may be sold in hydrogel and/or liquid form as a drug.

“Patent Expenses” means the out of pocket fees, expenses, and disbursements and outside counsel and agent fees incurred by Oculus in preparing, filing, prosecuting and maintaining Oculus Patents, including Oculus’s costs of patent interference, opposition and nullity proceedings relating thereto.

“Patents” means all patents, patent applications and patent applications hereinafter filed in any country of the world, including any continuation, continuation-in-part, division, provisional or any substitute applications, any patent issued with respect to any such patent applications, any reissue, reexamination, renewal or extension (including any supplemental patent certificate) of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent, and all foreign counterparts of any of the foregoing.

“Pipeline Products” means all products, services and business opportunities being developed or disclosed, to be developed by Oculus as of the Effective Date, as evidenced by Oculus’ books and records and as disclosed to Ruthigen as of the Effective Date.

“Pre-clinical Development” means all activities relating to the planning and execution of non-human studies conducted in *in vitro* or in relevant *in vivo* animal models directed toward obtaining Regulatory Approval of the Product in the Field in the Territory. This includes pre-clinical testing, pharmacokinetics, toxicology, safety testing, test method development and stability testing, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, clinical trial design and operations, preparing and filing documentary and medical writing directly related to Pre-clinical Development activities, and related regulatory affairs.

\* Confidential material redacted and separately filed with the Commission.



“Product” means any sterile prescription drug product in liquid, gel or gas formulation for use in the Field in the Territory, which product includes as the active ingredient a formulation of the Substance having at least either [ ]\* per [ ]\* of [ ]\* at the time of commercial release, and has a decrease of hypochlorous acid of less than [ ]\*%, in active ingredient concentration over a [ ]\* ([ ]\*) month shelf life pursuant to product release studies, any services employing such product, and where the manufacture, use, sale or import of such product or service would either (i) infringe, absent the licenses granted by Oculus to Ruthigen hereunder, a Valid Claim within the Oculus Patents; and/or (ii) misappropriate, absent the licenses granted by Oculus to Ruthigen hereunder, the Oculus Know-how. The Product may, at Ruthigen’s option, include additional chemicals or compounds such as magnesium.

“Regulatory Approval” means the approval by the FDA and any other Regulatory Authority necessary for the Commercialization of the Product in the Field in the Territory.

“Regulatory Authority” means the FDA or any other regulatory authority inside or outside the United States.

“Ruthigen Method of Manufacturing” means any method of manufacturing certain liquids incorporating chlorine that generates a product that, except as otherwise expressly provided in this Agreement, (i) has a minimum of either [ ]\* per [ ]\* of [ ]\* at the time of commercial release, and (ii) with or without chemical additives has a decrease of less than [ ]\*% in active ingredient concentration over a [ ]\* ([ ]\*) month shelf life pursuant to product release studies, or such other change in concentration over a [ ]\* ([ ]\*) month shelf life as the Parties agree pursuant to Section 2.4(c). The Ruthigen Method of Manufacturing does not include the Oculus Method of Manufacturing.

“Specifications” shall mean the requirements, specifications, tests, standard test methods, and acceptance limits for qualitative and quantitative characteristics of the Product and the Substance as set out in Schedule 2 (attached hereto and made a part hereof), as same may be amended from time to time by mutual written agreement of the Parties.

“Substance” means the proprietary chemical formulation of hypochlorous acid produced by either the Oculus Method of Manufacturing or the Ruthigen Method of Manufacturing, a non-limiting example of which is RUT58-60, a formulation containing at least [ ]\* per [ ]\* of [ ]\* at time of commercial release.

“Territory” means the United States, Canada, the European Union and Japan.

“Third Party” means any entity other than Oculus or Ruthigen and their respective Affiliates.

“United States” means the United States of America and its territories and commonwealths and possessions, including without limitation the Commonwealth of Puerto Rico.

“Urinary Tract Infection Product” means a non-sterile medical device for use in the mechanical flushing of a bladder, as defined by FDA regulations, and subject to the Parties’ prior written agreement regarding packaging, volume and pricing, which includes a formulation having no greater than [ ]\*, is manufactured using the Oculus Method of Manufacturing, and has a decrease at a rate that is greater than [ ]\*% in [ ]\* concentration over a [ ]\* month shelf pursuant to product release studies, and the [ ]\* per [ ]\* of [ ]\* will be mutually agreed upon. If required by FDA, the product shall be sterile and/ or a combination product. Notwithstanding anything to the contrary herein, Oculus may only sell, offer for sale and have sold Urinary Tract Infection Products within the following fields or indications: (a) burn patients under the humanitarian device exemption, (b) spinal cord injury patients outside of the hospital, and (c) nursing homes patients.

\* Confidential material redacted and separately filed with the Commission.

“Valid Claim” shall mean a claim in an issued, unexpired Oculus Patent which has not been abandoned, withdrawn, canceled or disclaimed, nor held invalid or unenforceable by a court of competent jurisdiction in an unappealed or unappealable decision or through disclaimer or otherwise, and is not lost through an interference proceeding.

For all purposes of this Agreement, except as otherwise expressly provided or unless the context clearly requires otherwise: (i) the terms defined herein include the plural as well as the singular and vice-versa; (ii) any reference to a “Schedule”, and “Article” or a “Section” refers to a Schedule, an Article or a Section, as the case may be, of this Agreement; (iii) the Schedules hereto form part of this Agreement and are incorporated herein by this reference; (iv) all references to this Agreement and the words “herein”, “hereof”, “hereto” and “hereunder” and other words of similar import refer to this Agreement as a whole and not to any particular Schedule, Article, Section, or other subdivision; (v) all Article and Section headings (captions) are for convenience only and shall not affect the interpretation or construction of this Agreement, (vii) the words “including,” “included” and “includes” mean inclusion without limitation; and (viii) in the event of any conflict between the terms in the body of the Agreement and the terms in the Schedules, the terms of the Agreement shall prevail to the extent that there is such a conflict.

## **Article II** **Licenses to Patents and Know-How**

### 2.1 License.

(a) As of the Effective Date of this Agreement, and subject to the terms and conditions hereof, Oculus hereby grants to Ruthigen.

(i) the exclusive (even as to Oculus) right and license under all of Oculus’ right, title and interest in and to the Oculus Patents and the Oculus Know-how (including without limitation the Oculus Method of Manufacturing and the Ruthigen Method of Manufacturing) to the extent necessary to Develop and Commercialize Products in the Territory and within the Field.

(ii) the co-exclusive (i.e., exclusive as between Oculus and Ruthigen) right and license under all of Oculus’ right, title and interest in and to the Oculus Patents and the Oculus Know-how to use the Oculus Method of Manufacturing to Manufacture the Substance and/or Product (as defined elsewhere in this Agreement).

(b) Oculus hereby grants to Ruthigen an option (the “Manufacturing Option”), subject to receipt by Oculus of a written notice of Manufacturing Option exercise and payment of the Equipment Purchase Price to purchase one or more units of Manufacturing Equipment, at Ruthigen’s discretion. Upon exercise of the Manufacturing Option, Ruthigen is automatically granted a co-exclusive, nonsublicensable, royalty-bearing right and license under the Oculus Patents and the Oculus Know-how to use the Oculus Method of Manufacturing and the Ruthigen Method of Manufacturing to Manufacture the Product (as applicable) for Development and Commercialization of the Product in the Field in the Territory (the “Manufacturing License”). Ruthigen’s appointment of a contract manufacturing organization to Manufacture Products shall not be deemed a sublicense in contravention of this subsection 2.1(b).

## 2.2 OOS Option.

(a) Oculus hereby grants to Ruthigen an exclusive option (the “OOS Option”), subject to receipt by Oculus of a written notice of OOS Option exercise and payment of the OOS License Fee (as defined below), to extend the Field in the Territory of the license granted to Ruthigen in Section 2.1(a) above to include the Indications. Oculus reserves the worldwide right to make, have made, use, sell, offer to sell, have sold and import products and services for the Indications in all fields (but not to authorize Third Parties to make, use, sell, have sold or import products and services for the Indications in the Field in the Territory. Ruthigen may exercise the OOS Option by delivering to Oculus a written notice of intent to exercise prior to the fifth (5<sup>th</sup>) anniversary of the Effective date, and such exercise shall be effective upon Oculus’ receipt of payment in full of the OOS License Fee. Upon exercise of the OOS Option, the Field shall automatically be extended to include the Indications and subject to the license set forth in Section 2.1(a), subject, however, to existing licenses and distribution arrangements as of such date of exercise. If and when Ruthigen exercises the OOS Option, Oculus shall cease all activities in respect of the Indications in the Field in the Territory.

(b) The OOS Option License Fee shall be (i) at any time prior to the two-year anniversary of the Effective Date, ten million dollars (\$10,000,000), and (ii) at any time after two years after the Effective Date and prior to the fifth (5<sup>th</sup>) anniversary of the Effective Date, Ruthigen shall pay ten million dollars (\$10,000,000) plus all Out of Pocket Costs expended or incurred by Oculus in the development of one or more Products for any of the Indications until the date of exercise (the “OOS License Fee”). The OOS License Fee shall be payable by Ruthigen in cash within thirty (30) days after Ruthigen delivers the written notice of exercise to Oculus. For purposes of the OOS Option, “Out of Pocket Cost” means a cost or expense paid to non-employee service providers or providers of materials that can be completely attributed to the Development of a Product for any of the Indications and includes materials, outside labor and services and expenses, but excludes administrative expenses, overhead and depreciation.

(c) Oculus will maintain complete and accurate records relevant to the Out of Pocket Cost. Oculus shall make the records available for inspection to Ruthigen promptly after receipt of Ruthigen’s written notice of exercise. If Ruthigen disputes the accuracy of such records, Ruthigen may require that the records be inspected by a certified public accountant or chartered accountant selected by Ruthigen (subject to the consent of Oculus not to be unreasonably withheld or delayed), for the sole purpose of verifying for Ruthigen the correctness of calculations and classifications of such Out of Pocket Cost. Ruthigen shall bear its own costs related to such audit. Any records or accounting information received from Oculus shall be Confidential Information for the purposes of Article X.

2.3 Retention of Rights. For clarity and subject at all times to the rights granted to Ruthigen and the restrictions upon Oculus set forth in Section 2.1, Oculus retains at all times (except as set forth in Section 2.4(a)) all rights under the Oculus Patents, Oculus Know-how, Oculus Method of Manufacturing and Ruthigen Method of Manufacturing not licensed to Ruthigen hereunder, including, without limitation:

(i) the exclusive worldwide right to use the Oculus Method of Manufacturing and the Ruthigen Method of Manufacture to manufacture the Substance and Products for use outside the Field and outside the Territory; and

(ii) the exclusive right to use the Oculus Method of Manufacturing and the Ruthigen Method of Manufacturing to make, have made, use, sell, offer to sell, have sold and import any product outside the Territory, and the exclusive right to use the Oculus Method of Manufacturing to make, have made, use, sell, offer to sell, have sold and import any product and service for use outside the Field;

Oculus shall not sell, offer to sell or authorize the sale of the Substance or Product to any person or entity if Oculus has knowledge that such person or entity intends to import the Substance or Products into the Territory, or intends to use it within the Field within the Territory.

#### 2.4 Non-Compete.

(a) Oculus shall not, and shall not authorize, sublicense, appoint or engage any person or entity to, use the Oculus Method of Manufacturing or the Ruthigen Method of Manufacturing to make, have made, use, sell, offer to sell, have sold or import in the Territory (i) any drug or sterile device product, in each case with greater than [ ]\* of [ ]\* with greater than [ ]\*% degradation in [ ]\* concentration over a [ ]\* ([ ]\*) month shelf life pursuant to product release studies in liquid form; or (ii) any product or service that competes, directly or indirectly, with any Product developed, manufactured and/or commercialized by Ruthigen in the Territory in the Field as permitted in this Agreement. The Parties acknowledge and agree that (i) Oculus' sale of Products to Ruthigen and its Affiliates and sublicenses hereunder; (ii) the worldwide making, having made, use, sale, offer to sell, having sold and import by Oculus of (A) Oculus Products, (B) Urinary Tract Infection Products; (C) the products and services specifically acknowledged as being not included in the definition of "Invasive" herein; (D) Pipeline Products; (iii) the making, having made, use, sale, offer to sell, having sold and import by Oculus of products and services related to the Indications outside the Territory; and (iv) Oculus's exercise of its retained rights, shall not constitute a breach of this Section 2.4(a). If, as a result of a Change in Control of Oculus that occurs after the Effective Date, a Third Party, other than a Third Party that derives more than fifty percent (50%) of its revenues from the commercialization of one or more products with hypochlorous acid as its/their active ingredient using a method of manufacturing similar to the Oculus Method of Manufacture or the Ruthigen Method of Manufacturing and is headquartered within Japan, becomes Oculus' Affiliate as a result of such Change in Control, then such Third Party's products or services marketed or sold by such Third Party as of the date of such Change in Control that compete with Ruthigen's products or services in contravention of this Section 2.4(a) shall not qualify as a breach of this Section 2.4(a). If, as a result of a Change in Control in Ruthigen described in Section 2.4(b), products or services marketed or sold by a Third Party which becomes a Ruthigen Affiliate as a result of such Change in Control that compete with the products and services of Oculus as described in Section 2.4(b), then Oculus shall not be restricted from marketing or selling any product or service that competes against such Third Party products or services.

(b) Ruthigen shall not, and shall not authorize, sublicense, appoint or engage any person or entity to, to Develop, Manufacture or Commercialize any device whatsoever, or any product that competes, directly or indirectly, with any product actively marketed by Oculus as of the Effective Date, or, for the avoidance of doubt, with the Oculus Products; Urinary Tract Infection Products; the products and services specifically acknowledged as being not included in the definition of "Invasive" herein; Pipeline Products; products and services related to the Indications outside the Territory and, prior to Ruthigen's exercise of the OOS Option, if ever, inside the Territory. If, as a result of a Change in Control of Ruthigen that occurs after the Effective Date, a Third Party, other than a Third Party that derives more than fifty percent (50%) of its revenues from the commercialization of one or more products with hypochlorous acid as its/their active ingredient using a method of manufacturing similar to the Oculus Method of Manufacture or the Ruthigen Method of Manufacturing and is headquartered within Japan, becomes Ruthigen's Affiliate as a result of such Change in Control, then such Third Party's products or services marketed or sold by such Third Party as of the date of such Change in Control that compete with Oculus' products or services in contravention of this Section 2.4(b) shall not qualify as a breach of this Section 2.4(b). If, as a result of a Change in Control in Oculus described in Section 2.4(a), products or services marketed or sold by a Third Party which becomes an Oculus Affiliate as a result of such Change in Control that compete with the products and services of Ruthigen as described in Section 2.4(a), then Ruthigen shall not be restricted from marketing or selling any product or service that competes against such Third Party products or services.

\* Confidential material redacted and separately filed with the Commission.

(c) The Parties agree that, if efficacy or safety issues arise in development regarding Product or Urinary Tract Product formulations, the Parties will negotiate in good faith to agree to an adjustment of the concentration allowances and/or change in concentration over a [ ]\* ([ ]\*) month shelf life to enable the formulations to meet FDA requirements, and such agreement shall be set forth in a written amendment to this Agreement signed by each of the Parties.

2.5 Patents. A list of the Oculus Patents identified as of the Effective Date is attached hereto as Schedule 1. If at any time during the course of this Agreement any additional Patents are Controlled by Oculus that include any claims that are reasonably necessary or desirable for the Manufacture, Development and/or Commercialization of the Substance and/or Product in the Territory in the Field, such shall be added to the list attached hereto as Schedule 1.

2.6 Limited Use. Ruthigen covenants that it shall not use any of the Oculus Know-how or Oculus Patents to carry out any activity or exercise any right other than those expressly licensed by Oculus to Ruthigen pursuant to this Agreement. Oculus covenants it shall not use the Ruthigen Method of Manufacture other than as permitted in this Article II.

**Article III**  
**Development**

3.1 Development.

(a) Ruthigen shall be solely responsible for and bear all costs of all Development of the Product in the Field in the Territory.

(b) Ruthigen shall use its Commercially Reasonable Efforts to Develop the Product in accordance with the timelines set out in the Development and Commercialization Plan and to obtain Regulatory Approval for the Product in the Field in the Territory pursuant to Development and Commercialization Plan and bring the Product to market in the Territory as promptly as possible.

3.2 Clinical Development Applications, Drug Approval Application.

(a) As between the Parties, Ruthigen shall be solely responsible for the preparation, filing and prosecution of applications for permission to conduct Development and Commercialization of Products in the Field in the Territory.

(b) As between the Parties, Ruthigen shall be solely responsible for the preparation, filing and prosecution of the Drug Approval Application and shall seek Regulatory Approval for the Product in the Field in the Territory, including preparing all reports necessary as part of the Drug Approval Application. The Drug Approval Application shall be filed in the name of Ruthigen.

(c) Cooperation. Ruthigen shall inform and consult with Oculus prior to each regulatory submission of a Product to a Regulatory Authority, provided, however, that prior to and following Regulatory Approval, Ruthigen shall be solely responsible for interactions with the Regulatory Authority.

(d) Application and Approval. As between the Parties, Ruthigen shall be the legal and beneficial owner of the Drug Approval Application and related Regulatory Approval in the Territory. If either Party receives notice of any reportable adverse event or similar regulatory notice within any country within the Territory, then both Parties will comply with their respective regulatory requirements and confer on the issue in good faith.

\* Confidential material redacted and separately filed with the Commission.

3.3 Support by Oculus. At Ruthigen's request, Oculus shall provide Ruthigen with reasonable support in the form of consulting services, subject to Oculus personnel and scheduling constraints, directed toward securing and maintaining Regulatory Approval, at such rates for each such employee as set forth in the Shared Services Agreement to be entered into by and between Oculus and Ruthigen (the "Shared Services Agreement").

3.4 Communications. All material communications between the Parties regarding this Agreement shall be conducted by the Parties' designated senior management personnel whom are reasonably acceptable to the other Party.

#### **Article IV** **Commercialization**

4.1 Ruthigen as Sole Commercialization Party. Ruthigen shall have the sole and exclusive right to Commercialize the Product, either by itself or through its Affiliates and sublicensees in the Field in the Territory.

4.2 Development and Commercialization Plan. The expected Commercialization to be conducted by Ruthigen pursuant to this Article IV shall be set out in the Development and Commercialization Plan attached hereto as Schedule 3. Ruthigen may, from time to time, modify the Development and Commercialization Plan in its discretion. For so long as Ruthigen and Oculus are members of the same Consolidated Group, Ruthigen shall give Oculus prompt notice of any material deviation from the Development and Commercialization Plan and any material redefinition of Commercialization goals and strategy.

4.3 Commercialization Efforts. Ruthigen agrees to use Commercially Reasonable Efforts with respect to the Commercialization of Products in the Field in the Territory as provided hereunder. Without limiting the generality of the foregoing, Ruthigen shall determine the pricing for the Product at its sole discretion.

4.4 Marketing and Sales Infrastructure. Ruthigen agrees to Commercialize the Product in the Field in the Territory on the basis of a qualified marketing and sales infrastructure designed, in part, to Commercialize the Product.

4.5 Restrictions on Commercialization of Products. Ruthigen will not seek customers or establish any branch or commercialization depot for the Product in any country which is outside the Territory unless such activity is required by law. Ruthigen will not knowingly supply the Product to any customer outside the Territory or to any customer in the Territory for resale outside the Territory unless such supply is required by law. If Ruthigen becomes aware that any Product sold by it, its Affiliate or sublicensee has been transferred or sold outside the Territory then, subject to Ruthigen's obligations of confidentiality, if any, owed to a Third Party, Ruthigen shall promptly notify Oculus thereof. If Oculus notifies Ruthigen that any Product sold by Ruthigen or its Affiliates or sublicensees has been or is being supplied to a customer or other Third Party outside the Territory, Ruthigen shall seek to confirm such activity and, if Ruthigen confirms such activity, then Ruthigen shall immediately cease its, its Affiliates' and its sublicensees' supply of Product to such customer or Third Party until Ruthigen confirms, in its reasonable discretion, that such customer or Third Party will no longer use the Product outside the Territory. Neither Oculus nor any of its Affiliates or licensees will seek customers or establish any branch or commercialization depot for the Product in the Field in the Territory. Oculus and its Affiliates and licensees will not knowingly supply Product to any customer in the Territory or outside the Territory for resale in the Field in the Territory unless such supply is in compliance with the terms of this Agreement or is required by law. If Oculus becomes aware that any Product sold by it, its Affiliate or licensee has been transferred or sold within the Territory then, subject to Oculus' obligations of confidentiality, if any, owed to a Third Party, Oculus shall promptly notify Ruthigen thereof. If Ruthigen notifies Oculus that any Product sold by Oculus or its Affiliates or licensees has been or is being supplied to a customer or other Third Party within the Territory, Oculus shall seek to confirm such activity, and if Oculus confirms such activity, then Oculus shall immediately cease its, its Affiliates' and its licensees' supply of Product to such customer or Third Party until Oculus confirms, in its reasonable discretion, that such customer or Third Party will no longer use the Product within the Territory.

4.6 Non-Solicitation. Each of the Parties agrees that for so long as Ruthigen and Oculus are members of the same Consolidated Group, it shall not solicit for employment any employee of the other Party who is or was employed by such other Party at such time and during the twelve (12)-month period immediately preceding the Effective Date. General public media advertising or solicitations for employment not specifically targeted towards the other Party's employees shall not be a breach of this Section. Notwithstanding the foregoing, Ruthigen agrees that it will not solicit, hire, employ, engage or retain any member of Oculus' research and development group.

**Article V**  
**Cooperation Between the Parties**

5.1 Formulation of Development and Commercialization Policies, Strategy and Goals. Each Party will designate one member of senior management who has experience with the Development and Commercialization of the technology licensed in Section 2.1, and who is reasonably acceptable to the other Party, to confer with the other Party in its respective policy, strategy and goal formulation for Development, Manufacture and Commercialization of its respective products based on hypochlorous acid, and such persons shall confer from time to time to discuss and review the Parties' mutual strategies and goals and the Parties' performance of this Agreement.

5.2 Coordination: Ruthigen and Oculus shall, from time to time with respect to their respective products and services based on hypochlorous acid: (a) discuss the status of obtaining the Regulatory Approval; (b) discuss the Commercialization of the product, including the progress and conduct of the Commercialization, meeting Commercialization goals and dealing with obstacles to successful Commercialization; (c) discuss actions planned by Ruthigen in respect of the Product where Ruthigen has reason to believe such actions could reasonably be expected to have a material adverse impact on the Product in the Territory or outside the Territory; (d) discuss in good faith if and when to shift the responsibility for Product patent prosecution to Ruthigen; (e) discuss in good faith the differentiation of packaging for the Products and Oculus's products to ensure that the packaging does not render the products confusingly similar; and (f) discuss in good faith other issues relating to the Commercialization of the product in the Territory and outside the Territory. All discussions and other activities contemplated by this Article V shall be subject to the confidentiality obligations of Article X of this Agreement. Notwithstanding the foregoing, neither Party shall be obligated to disclose any of its information to the other Party to the extent such disclosure may conflict with its disclosure and reporting obligations as a public company.

**Article VI**  
**Manufacture of Clinical and Commercial Supply**

6.1 Manufacture of Product. Oculus shall Manufacture (and not appoint any Third Party to Manufacture) and supply to Ruthigen as and when reasonably requested, Products in accordance with the relevant Specifications, and subject to the terms of this Article VI.

6.2 Standard of Manufacturing. Oculus warrants and represents that it shall Manufacture all Products in the Territory in compliance and accordance with the requirements of the appropriate Regulatory Authority to Manufacture drug products under cGMP conditions and in accordance with the Specifications and all applicable laws, and that each Product shall be free of manufacturing defects. Upon delivery of the Product, Oculus shall provide to Ruthigen all original batch records, reject samples, and relevant documents including but not limited to as required under cGMP for lot to lot traceability of materials, and a certificate of analysis confirming all Products meet the Specifications, and any additional information as reasonably requested by Ruthigen to allow it to comply with applicable laws, rules and regulations. Oculus shall notify Ruthigen and/or provide any information, including but not limited to any regulatory results or current Good Manufacturing Practices issues, within three (3) Business Days of discovering such information. Oculus shall promptly report any and all deviations during Manufacturing of Products to Ruthigen. All deviations, not limited to Specifications, Manufacturing, process, equipment and material controls shall require Ruthigen's prior written approval. Ruthigen shall have the right, upon reasonable advance notice and during normal business hours, to make a representative or auditor available to observe the Manufacturing process and environment, Product storage conditions and related processes or documentation. Ruthigen will not be liable for payment for any Products which do not meet the requirements of this Agreement, which Products shall be promptly replaced by Oculus at its own expense or, if Oculus cannot promptly replace such Products, then Oculus shall immediately refund all amounts paid by Ruthigen in respect of such nonconforming Products.

6.3 Forecast. Within a reasonable time after the Effective Date, but in no event more than thirty (30) days prior to each calendar quarter and on a calendar quarterly basis thereafter, Ruthigen shall provide a non-binding, rolling forecast of purchases of the Product for the next two (2) calendar quarters.

6.4 Purchase Orders. All purchase orders to be fulfilled by Oculus shall contain pricing, requested shipment schedule, delivery address, requested carrier and quantity terms. Oculus will acknowledge each purchase order within two (2) Business Days (and its failure to acknowledge a purchase order within such time shall be deemed acknowledgment thereof). Oculus will receive purchase orders, fulfill and ship orders from Petaluma, California. Oculus will fulfill all of Ruthigen's purchase orders conforming to the then-current quarter of forecast and will use commercially reasonable efforts to fulfill any amounts requested in excess of the forecast. The lead time for Products is sixty (60) days and Oculus will ship all Products by the delivery date set forth in the relevant purchase order, provided that Oculus received the relevant purchase order within such lead time. If Oculus must allocate its supply of Products for causes beyond its reasonable control, it shall immediately notify Ruthigen, and Ruthigen's orders shall be filled on no less than an equal basis with Oculus's other top-tier/preferred customers and distributors. When acknowledgement of receipt and acceptance of a purchase order is made by Oculus (either by written notice or by shipment of the ordered Product), the purchase order or delivery schedule shall be deemed a commitment to purchase and sell the Product pursuant to the terms of this Agreement.

6.5 Pricing. Ruthigen shall purchase from Oculus, and Oculus shall sell to Ruthigen, Product pursuant to this Article VI at a purchase price equal to Oculus's Cost of Goods plus 20%.

6.6 Payment Terms. Payment terms to Oculus from Ruthigen for Product are thirty (30) days after the shipment of Product from Oculus to Ruthigen;

6.7 Branding of Product. Ruthigen shall have the right to market and brand the Product in the Territory using, in its discretion, a Ruthigen trademark or Ruthigen Affiliate trademarks, and/or to appoint distributors or resellers to brand the Product in the Territory using their trademarks.

6.8 Delivery of Product. Cost of transportation from Oculus to Ruthigen's designated plant will be shared equally by the parties.

6.9 Packaging. Oculus shall package the Product for shipment to Ruthigen in packaging chosen by Ruthigen.

6.10 Risk of Loss or Damage. Title and risk of loss shall be borne by Oculus until delivery to Ruthigen's designated plant.

6.11 Cancellation; Rescheduling. Ruthigen may not cancel any shipment under a purchase order once the purchase order is accepted by Oculus. Ruthigen may reschedule such shipment as long as notice is provided fifteen (15) days prior to the scheduled Manufacturing of the batch of Substance. Such rescheduling shall be for no longer than sixty (60) days.



6.12 Changes to Manufacturing. Oculus shall not make any changes to the Manufacturing process or equipment for Products without the approval of Ruthigen. At the request of Ruthigen, Oculus shall provide document of any proposed changes for review by the Parties.

6.13 Manufacturing Equipment. Ruthigen may, at any time upon notice to Oculus, purchase one or more units of Manufacturing Equipment, at Ruthigen's discretion, and Oculus shall deliver the Manufacturing Equipment to Ruthigen, at Ruthigen's expense, within sixty (60) days of receipt of payment therefor.

(a) Ruthigen shall purchase the Manufacturing Equipment at Oculus's Cost of Goods plus 20% (the "Equipment Purchase Price").

(b) Promptly upon the Effective Date, Oculus shall disclose and provide to Ruthigen all Oculus Know-how regarding the Oculus Method of Manufacturing and the Ruthigen Method of Manufacturing which is available to Oculus and required for the Manufacture of the Product and Substance. Oculus will promptly deliver to Ruthigen updates to such Know-how as Oculus may own or Control thereafter during the term of this Agreement, including providing access to Oculus key employees and documents. All such information shall be subject to the confidentiality provisions of Article X. Oculus will also provide training and access to Oculus personnel in support of this technology transfer as requested by Ruthigen from time to time, pursuant to the Shared Services Agreement.

(c) Ruthigen shall Manufacture the Products in compliance and accordance with current Good Manufacturing Practices and all applicable laws, regulations and approvals.

(d) Oculus shall have the right to repurchase the Manufacturing Equipment (i) upon a Change in Control of Ruthigen involving an acquiring Third Party that sells hypochlorous-acid products, or that competes with Oculus as a manufacturer of hypochlorous acid formulations or processes involving electrolysis, unless in either case such Third Party is headquartered in Japan, (ii) upon Ruthigen's cessation of business, or (iii) upon initiation by Ruthigen of insolvency proceedings; and in each case, at the Equipment Purchase Price less accumulated depreciation.

(e) Ruthigen shall have the right to purchase Oculus' entire inventory of Manufacturing Equipment (i) upon a Change in Control of Oculus involving an acquiring Third Party that sells hypochlorous-acid products, or that competes with Ruthigen as a manufacturer of hypochlorous acid formulations or processes involving electrolysis, unless in either case such Third Party is headquartered in Japan, (ii) upon Oculus' cessation of business, or (iii) upon initiation by Oculus of insolvency proceedings; and in each case, at the Equipment Purchase Price less accumulated depreciation.

6.14 Limitation on Damages. The Parties agree that Oculus shall not be liable to Ruthigen for any indirect, special or consequential damages (including without limitation any damages arising from lost profits) arising out of or in connection with any shortfall or disruption of supply of Product or Substance for which Ruthigen had placed a firm order.

**Article VII**  
**Milestone Fees**

7.1 Milestone Payments. In partial consideration for the licenses granted to Ruthigen herein, Ruthigen shall pay to Oculus the milestone fees identified below with respect to the first Product to reach the first milestone event only, as provided below.

	<b>Milestone Event</b>	<b>Milestone Payment</b>
1.	Upon IND filing	One Million Dollars (\$1,000,000)
2.	Upon first patient enrollment of Phase I/II	One Million Dollars (\$1,000,000)
3.	Upon enrollment of first patient post-safety review of run in during Phase II	One Million Dollars (\$1,000,000)
4.	Upon first patient enrollment of first pivotal trial	Two Million Dollars (\$2,000,000)
5.	Upon Ruthigen's scheduling its first post-pivotal trial meeting / call with the FDA	One Million Dollars (\$1,000,000)
6.	Upon first patient enrollment of second pivotal trial	Two Million Dollars (\$2,000,000)

Each milestone payment shall accrue upon the occurrence of the corresponding milestone event.

For any and all milestone events that occur on or prior to the closing of an IPO, if Ruthigen's IPO results in gross proceeds of at least twelve million dollars (\$12,000,000) (a "Qualifying IPO"), then Ruthigen shall pay to Oculus in cash each milestone payment accruing on such milestone event(s) within fifteen (15) days of the occurrence of the milestone.

However, if the IPO is not a Qualifying IPO, then each milestone payment shall accrue upon the occurrence of the milestone event, but Ruthigen shall pay Oculus the corresponding milestone payment as follows: Ruthigen will pay to Oculus in cash (i) all accrued milestone payments within fifteen (15) days after the closing of the Sale Transaction which results in the aggregate Gross Value from such Sale Transaction and all previously closed Sale Transactions, totaling twelve million dollars (\$12,000,000), and (ii) all milestone payments accruing after the closing of such Sale Transaction within fifteen (15) days of the corresponding milestone event.

"Sale Transaction" means any sale (whether in one or a series of transactions) of all or a substantial portion of the assets of Ruthigen; the private or public sale of the capital stock of Ruthigen (including, without limitation, common stock, preferred stock, derivative securities or convertible debt), and including an IPO); any merger, reverse merger, non- pro rata spin-off, reverse spin-off, or other business combination involving Ruthigen; any recapitalization, restructuring or liquidation of Ruthigen or any other form of transaction or disposition that results in the effective sale, transfer or other disposition of ownership or control over a substantial portion of one or more of the principal businesses or operations of Ruthigen; any loan, credit facility, equipment financing, factoring, or other loan transactions with lenders or financial institutions; or any licensing agreement, co-development agreement, joint-venture, partnership, similar business combination or similar business arrangement involving Ruthigen. For the avoidance of doubt, "Sale Transaction" shall not include any issuance sale or distribution of (i) the capital stock of Ruthigen held by Oculus; (ii) shares of common stock or common stock equivalents issued or issuable to directors, officers, employees or consultants of Ruthigen in connection with their service as directors or officers of Ruthigen, their employment by Ruthigen or their retention as consultants by Ruthigen pursuant to any benefit plans, programs or agreements; (iii) shares of common stock or common stock equivalents issued (or issuable upon the exercise of rights, options or warrants outstanding from time to time) to financial institutions, equipment lessors, brokers or similar persons in connection with commercial credit arrangements, equipment financings, commercial property lease transactions or similar transactions, and (iv) shares of common stock or common stock equivalents issued (or issuable upon exercise of rights, options or warrants outstanding from time to time) for bona fide services, to the extent not included in any other Sale Transaction.

“**Gross Value**” means (i)(A) in the case of a Sale Transaction involving the capital stock of Ruthigen, the total fair market value (at the time of announcement) of all consideration paid or payable, or otherwise to be distributed, directly or indirectly, in respect of Ruthigen common share in connection with the Sale Transaction multiplied by Ruthigen’s Fully Diluted Shares Outstanding (as defined below); (B) in the case of a Sale Transaction involving assets of Ruthigen, the total fair market value (at the time of announcement) of all consideration paid or payable, or otherwise to be distributed, directly or indirectly, to Ruthigen or its shareholders in connection with the Sale Transaction; (C) in the case of a Sale Transaction involving the incurrence of debt, all amounts received by or made available to Ruthigen; and (D) in the case of a Sale Transaction involving any licensing agreement, co-development agreement, joint-venture, partnership, similar business combination or similar business arrangement, the total fair market value (at the time of announcement) of all consideration paid or payable (including, without limitation, up-front payments, license fees and milestone payments), or otherwise to be distributed, directly or indirectly, to Ruthigen or its shareholders in connection with the Sale Transaction.

In the case of a Sale Transaction in which the consideration consists of another company’s publicly traded securities, the fair market value of the consideration shall be calculated using the average of the closing prices of such publicly traded security for each of the 10 consecutive trading days up to and including the second trading day immediately preceding the announcement of the Sale Transaction.

Any amounts to be paid contingent upon future events shall be estimated for the purposes of calculating the Gross Value in connection with the Sale Transaction at their expected net present value at the time of closing; any amounts held in escrow shall be deemed paid at closing.

“**Fully Diluted Shares Outstanding**” means the total number of shares of common stock outstanding plus the total number of shares of common stock issuable upon exercise, conversion or exchange of any outstanding securities exercisable, convertible or exchangeable into or for shares of common stock of Ruthigen including, without limitation, all outstanding stock options of Ruthigen. For purposes of this paragraph, consideration includes cash, securities, property, rights (contractual or otherwise), any dividends payable to shareholders of Ruthigen after the date hereof (other than normal, ordinary course, recurring dividends) and any other form of consideration.

### **Article VIII** **Royalties**

8.1 **Royalty Rate.** In further consideration of the rights and licenses granted to Ruthigen under Article II of this Agreement, during the term of this Agreement, Ruthigen shall pay to Oculus royalties based on Net Sales:

(a) in the United States in the following amounts:

3% of annual Net Sales (as calculated in this Section 8.1) of less than \$100,000,000 (One Hundred Million Dollars);

7% of annual Net Sales (as calculated in this Section 8.1) of \$100,000,000 (One Hundred Million Dollars) to \$250,000,000 (Two Hundred Fifty Million Dollars); and

12% of annual Net Sales (as calculated in this Section 8.1) of more than \$250,000,000 (Two Hundred Fifty Million Dollars).

Annual Net Sales shall be determined based on Ruthigen’s fiscal year.

(b) In Canada, Europe and Japan, 20% of all Net Sales.

The sums to be paid by Ruthigen pursuant to this Section 8.1 shall be in addition to the amounts payable by Ruthigen for the supply of the Product or Substance pursuant to Article VI above.

8.2 Royalty Term: Except where expressly provided otherwise in this Agreement, all royalties shall be calculated from the date of the First Commercial Sale of a Product until Ruthigen ceases to Commercialize the Product.

8.3 Payment Reports and Payments. Ruthigen shall make payments to Oculus monthly within thirty (30) days after the end of each calendar month in which Net Sales occurred, such period to be extended to forty five (45) days if sales are made and recorded by a sublicensee of Ruthigen. A report summarizing the Net Sales of the Product during the relevant month shall be delivered to Oculus within thirty (30) days or forty five (45) days (as applicable) following the end of each calendar month for which payments are due. Such reports shall constitute Confidential Information of both Parties.

8.4 Payments: Interest. Payments due under this Agreement shall be due on such date as specified in this Agreement and, in the event such date is not a Business Day, then the next succeeding Business Day, and shall be made by wire transfer of immediately available funds to a bank account designated by Oculus on or before the date payment is due. Any failure by Ruthigen to make a payment within thirty (30) days after the date when due, shall obligate Ruthigen to pay to Oculus computed interest, the interest period commencing on the due date and ending on the payment day, at a rate per annum equal to the Prime Rate as publicly announced by Bank of America plus three (3) percentage points, or the highest rate allowed by law, whichever is lower. Interest shall be compounded annually in arrears. Such interest shall be due and payable on the tender of the underlying principal payment.

8.5 Taxes. Oculus shall pay any and all taxes levied on account of all payments it receives under this Agreement. If laws or regulations require that taxes be withheld, Ruthigen will (i) deduct those taxes from all remittable payments, (ii) timely pay the taxes to the proper taxing authority, and (iii) send proof of payment to Oculus within thirty (30) days of receipt of confirmation of payment from the relevant taxing authority. Ruthigen agrees to make lawful and reasonable efforts to minimize such taxes to Oculus.

8.6 Payment Currency. Payments by Ruthigen under this Agreement shall be paid to Oculus in U.S. dollars.

8.7 Records of Revenues and Expenses: Audit.

(a) Ruthigen will maintain complete and accurate records relevant to the calculation of revenues under this Agreement. Not more often than once each year and upon at least thirty (30) days' notice, Ruthigen shall make such records available for inspection for the period required by applicable laws, but not less than the later of (i) two (2) years from creation of individual records, or (ii) the expiration of the period required by applicable laws and regulations, by an independent certified public accountant or chartered accountant selected by Oculus (subject to the consent of Ruthigen not to be unreasonably withheld or delayed), for the sole purpose of verifying for Oculus the correctness of calculations and classifications of such revenues under this Agreement. Oculus shall bear its own costs related to such audit; provided that, for any underpayments greater than five percent (5%) by Ruthigen, Ruthigen shall pay Oculus the amount of underpayment, interest as provided for in Section 8.4 from the time the amount was due and Oculus's reasonable out-of-pocket expenses for such audit. For any underpayments of less than five percent (5%) by Ruthigen, Ruthigen shall pay Oculus the amount of underpayment. Any overpayments by Ruthigen will be refunded to Ruthigen or credited to future royalties, at Ruthigen's discretion. Any records or accounting information received from Ruthigen shall be Confidential Information for the purposes of Article X. The accountant shall be required to enter into a nondisclosure agreement with Ruthigen covering all information learned or derived during such audit. Results of any such audit shall be provided to both Parties and shall also constitute Confidential Information for the purposes of Article X, provided that accountants are bound by appropriate confidentiality obligations and may only provide Oculus with evidence of any royalty payment discrepancies.

(b) If there is a dispute between the Parties following any audit performed pursuant to Section 8.7(a), either Party may refer the issue (an “Audit Disagreement”) to an internationally recognized independent certified public accountant or chartered accountant for resolution. In the event an Audit Disagreement is submitted for resolution by either Party, the Parties shall comply with the following procedures:

(i) the Party submitting the Audit Disagreement for resolution shall provide written notice to the other Party that it is invoking the procedures of this Section 8.7(b);

(ii) within ten (10) Business Days of the giving of such notice, the Parties shall jointly select a recognized international accounting firm to act as an independent expert to resolve such Audit Disagreement;

(iii) the Audit Disagreement submitted for resolution shall be described by the Parties to the independent expert, which description may be in written or oral form, within ten (10) Business Days of the selection of such independent expert;

(iv) the independent expert shall render a decision on the matter as soon as practicable;

(v) the decision of the independent expert shall be final and binding unless such Audit Disagreement involves alleged fraud, breach of this Agreement or construction or interpretation of any of the terms and conditions thereof; and

(vi) all fees and expenses of the independent expert, including any third party support staff or other costs incurred with respect to carrying out the procedures specified at the direction of the independent expert in connection with such Audit Disagreement, shall be borne by each Party in inverse proportion to the disputed amounts awarded to the Party by the independent expert through such decision (e.g. Oculus disputes \$100, the independent expert awards Oculus \$60, then Oculus pays forty percent (40%) and Ruthigen pays sixty percent (60%) of the independent expert’s costs).

#### **Article IX** **Adverse Drug Reactions**

9.1 Exchange of Information. Both parties agree to promptly exchange all information that relates to the safety of the Substance and/or Product and especially all adverse reactions and to comply with all applicable laws and regulations relating to the Substance and/or Product concerning drug safety.

9.2 Standard Operating Procedure. Ruthigen will adopt and follow the FDA-required standard operating procedures to conduct its United States FDA clinical trials.

9.3 Recall. Ruthigen shall have the exclusive right and authority to order a recall of the Product in response to FDA action or other event or incident. Each party agrees to notify the other immediately of any pending or threatened event which may lead to a recall or other removal or withdrawal of the Product from the Field in the Territory, including: (a) actual or threatened regulatory action by the FDA or any other governmental entity; or (b) safety concerns relating to the Product.

#### **Article X** **Confidentiality**

10.1 Confidentiality; Exceptions. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that the receiving Party shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than as provided for in this Agreement any Know-how and other information and materials furnished to it by the other Party or the other Party’s Affiliates or sublicensees pursuant to this Agreement, or any provisions of this Agreement that are the subject of an effective order of the Securities Exchange Commission granting confidential treatment pursuant to the Exchange Act of 1934 as amended (collectively “Confidential Information”), except to the extent that it can be established by the receiving Party that such Confidential Information:

(a) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the other Party; or

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party; or

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement.

(d) was disclosed to the receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the disclosing Party not to disclose such information to others; or

(e) was independently discovered or developed by the receiving Party without use of or reliance upon the other Party's Confidential Information as documented in its corporate records.

10.2 Specific Performance. The Parties recognize and agree that any breach by the receiving Party of its obligations contained in this Article X would cause irreparable harm to the disclosing party such that the disclosing Party could not be compensated for the harm by money damages alone. Therefore, the Parties agree that the provisions of this Article X shall be enforceable by specific performance, including injunctive relief.

10.3 Authorized Disclosure. Each Party may disclose Confidential Information of the other Party hereunder to the extent such disclosure is reasonably necessary in filing or prosecuting Product patent applications, prosecuting or defending Product litigation, filing or updating the Product drug approval applications, complying with applicable governmental laws, rules and regulations or conducting Development or Commercialization of Products, and each Party may disclose the other Party's Confidential Information to the extent such disclosure is reasonably necessary in complying with applicable governmental laws, rules or regulations. In each case, such Party will, except where impracticable for necessary disclosures, for example in the event of medical emergency, give reasonable advance notice to the other Party of such disclosure requirement and, except to the extent inappropriate in the case of patent applications, will use its reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed. Neither Party may disclose Confidential Information of the other Party to any person unless such person is subject to written obligations of confidentiality substantially similar to the Parties' obligations under Article X and only to the extent necessary to exercise such Party's rights, or fulfill its obligations, under this Agreement. Ruthigen may disclose Oculus' Know-how to Third Parties to the extent necessary for Ruthigen to Manufacture and have Manufactured the Substance and/or Products pursuant to, and in compliance with, the terms of this Agreement.

10.4 Negotiation Phase. The Parties agree that any disclosures made by either Party during the negotiations for this Agreement shall be deemed to have been made under, and be subject to the terms of this Agreement.

10.5 Publications. At any time while the Parties are members of the same Consolidated Group, any press release or other major publication by either Party relating to the Development, Commercialization or, if applicable, Manufacturing of the Product shall be provided to the other Party at least ten (10) Business Days (or five (5) Business Days in the case of a press release) in advance of publication. The other Party shall have the right to review and comment upon the publication and the Parties will cooperate in good faith to address any reasonable comments within such period.

10.6 Survival. This Article X shall survive the termination or expiration of this Agreement.

**Article XI**  
**Ownership of Intellectual Property, Patent Rights and Use of Name**

“Improvement” means any improvement, enhancement or modification of any technology claimed in the Oculus Patents or the Oculus Know-how that relates to the Substance and/or Product.

“Joint Patents” means all Patents claiming Joint Technology.

“Joint Technology” means all Technology developed jointly by the Parties in their performance of this Agreement. For the avoidance of doubt, the determination as to whether any Technology has been “solely” or “jointly” made shall be based upon whether employees, agents or independent contractors of a Party would be, or are properly named, as an inventor on a corresponding patent application under the patent laws of the country in which the relevant patent application is filed.

“Technology” means any information, data, materials, discovery, invention, idea, discovery, process, protocol, techniques, formulation, know-how (including accumulated skills and experience of a Party’s employees, officers, directors, consultants and contractors), trade secret, method, technological development, Improvement, work of authorship, computer software (including, but not limited to, source code and object or executable code), data, material, or sample; and documentation of any of the foregoing (including any records, raw data, concepts, information, designs, programs, formulae, or writings); in each case whether patentable or not, or susceptible to copyright, trade secret, or any other form of legal protection under applicable law and all other intellectual property rights or industrial rights, whether arising under the laws of any state, country or jurisdiction.

11.1 Ownership. Ruthigen hereby assigns to Oculus all of Ruthigen’s right, title and interest in and to (i) Improvements to Oculus Know-how and/or Oculus Patents invented by Ruthigen; and (ii) Joint Technology. All Improvements to Oculus Know-how and/or Oculus Patents Controlled by Oculus (whether invented by Ruthigen, Oculus and/or any Third Party, whether solely or jointly) and all Joint Technology is hereby licensed by Oculus to Ruthigen under the same terms as Oculus’ license to Ruthigen in Section 2.1(a). Oculus may practice Improvements developed or invented by Ruthigen and Joint Technology for all purposes other than to the extent expressly licensed to Ruthigen under Section 2.1(a), and subject to Oculus’ restrictions described in Section 2.1(b) and Section 2.4. Improvements and Joint Technology constitute both Parties’ Confidential Information.

11.2 Disclosure of Inventions. Ruthigen shall promptly disclose to Oculus any Improvement made solely by its own employees or consultants.

11.3 Patent Filings.

(a) Oculus, at its own expense, will prepare, file, prosecute and maintain all Oculus Patents and Joint Patents relating to the Substance and the Product in the Territory, and relating to Oculus Know-how. Oculus shall consult with Ruthigen in good faith regarding the preparation, filing, prosecution, and maintenance of the Oculus Patents and Joint Patents in the Territory, including the conduct of interferences, the defense of oppositions and other similar proceedings. Oculus will timely provide Ruthigen with a copy of any proposed patent application and any proposed response or submission to any patent office at least twenty (20) Business Days prior to the filing or response deadline and will consider in good faith all comments made by Ruthigen with respect to such draft response or submission. Oculus will keep Ruthigen reasonably informed of the status of such Patents, including, without limitation: (A) by providing Ruthigen with copies of all material communications received from or filed in patent office(s), or received from or sent to foreign attorneys, with respect to such filing, (B) by providing a status report at least annually and (C) by providing Ruthigen a reasonable time, but in any event not less than twenty (20) Business Days (subject to possible reductions as set forth in the prior sentence), prior to taking or failing to take any action that would materially affect the pendency of any such filing, with prior written notice of such proposed action or inaction so that Ruthigen has a reasonable opportunity to review and comment. In furtherance of the foregoing requirements, Oculus shall itself, or shall instruct and use reasonable efforts to ensure that its outside patent counsel, promptly forward to Ruthigen a copy of all correspondence received from or sent to any patent office relating to the Patents for which Ruthigen has a right of review and comment, and the Parties shall enter into a reasonable commonality of interest agreement if deemed advisable by their respective patent counsel.

(b) If Oculus elects not to file, prosecute or maintain an Oculus Patent or a Joint Patent in any given country within the Territory, then Oculus shall notify Ruthigen within an amount of time sufficiently in advance of any action or inaction that may jeopardize such Patent, in which case Ruthigen may, upon notice to Oculus, assume such filing, prosecution and maintenance of such Patent at its own expense.

(c) Each Party shall provide to the other Party all necessary declarations and cooperate with the other Party to enable Oculus Patents and Joint Patents to be filed, prosecuted and maintained. This Section 11.3 shall survive the termination of this Agreement for any reason.

#### 11.4 Enforcement Rights.

(a) Notification of Infringement. If either Party learns of any infringement or threatened infringement by a Third Party of the Oculus Patents or a Joint Patent, such Party shall promptly notify the other Party and shall provide such other Party with all available evidence of such infringement.

(b) Enforcement in the Territory. Ruthigen shall have the first right, but not the obligation, to defend and enforce Oculus Patents and Joint Patents against Third Parties in the Territory and to institute, prosecute and control any action or proceeding with respect to infringement of any Oculus Patents or Joint Patents covering the use of the Development, Manufacture or Commercialization of the Product being developed or marketed in the Territory, by counsel reasonably acceptable to Oculus. Oculus shall have the right, at its own expense, to be represented in any action by counsel of its own choice. If Ruthigen fails to bring an action or proceeding or otherwise take appropriate action to abate such infringement within a period of ninety (90) days of receipt of notice from Oculus requesting action, Oculus will have the right, at its own expense, to bring and control any such action or proceeding relating to Oculus Patents by counsel of its own choice, and Ruthigen will have the right to be represented in any such action by counsel of its own choice and at its own expense. If one Party brings any such action or proceeding, the other Party agrees to be joined as a party plaintiff if necessary to prosecute the action or proceeding and to give the first Party commercially reasonable assistance and authority to file and prosecute the suit. Compensatory damages awarded to Ruthigen shall be treated as Net Sales in the Territory and calendar month received, and all other damages awarded to a Party shall be retained by the Party bringing the action.

(c) Settlement with a Third Party. The Party that controls the prosecution of a given action shall also have the right to control settlement of such action, provided however, that no settlement shall be entered into without the written consent of the non-controlling Party if such settlement involves any payment or admission of liability by such non-controlling Party.



11.5 Use of Names. Neither Party shall use the name of the other Party in relation to this transaction in any public announcement, press release or other public document without the written consent of such other Party, which consent shall not be unreasonably withheld or delayed; provided however, that either Party may use the name of the other Party in any document filed with any Regulatory Authority.

**Article XII**  
**Representations and Warranties**

12.1 Each of the Parties represents and warrants to the other Party as follows:

The Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms. The execution, delivery and performance of the Agreement by such Party does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound, nor to such Party's knowledge, violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

12.2 Oculus hereby represents and warrants to Ruthigen that: (i) as of the Effective Date, Oculus has not granted any right or license to any other person or entity to make, use, sell, have sold or offer to sell Products for use in the Field within the Territory; and (ii) Oculus has the full right and legal capacity to transfer Know-how and grant the rights granted to Ruthigen hereunder.

12.3 DISCLAIMER. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS A WARRANTY OR REPRESENTATION, IN PARTICULAR, EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NOTHING SHALL BE CONSTRUED AS:

(a) A WARRANTY OR REPRESENTATION BY OCULUS AS TO THE VALIDITY OR SCOPE OF ANY OCULUS KNOW-HOW OR OCULUS PATENT OR TRADEMARK OR THAT THE EXERCISE OF THE PATENT RIGHTS WILL NOT INFRINGE UPON THE RIGHTS OF ANY THIRD PARTY;

(b) A REQUIREMENT THAT OCULUS SHALL FILE ANY PATENT APPLICATION OR TRADEMARK APPLICATION; SECURE ANY PATENT OR TRADEMARK APPLICATION, OR MAINTAIN ANY PATENT OR TRADEMARK APPLICATION IN FORCE;

(c) AN OBLIGATION BY EITHER PARTY TO BRING OR PROSECUTE ACTIONS OR SUITS AGAINST THIRD PARTIES FOR INFRINGEMENT;

(d) GRANTING BY IMPLICATION, ESTOPPEL, OR OTHERWISE BY OCULUS ANY LICENSES OR RIGHTS UNDER PATENTS OR KNOW-HOW OR TRADEMARK OTHER THAN AS EXPRESSLY SET FORTH IN THIS AGREEMENT;

(e) A REPRESENTATION OR WARRANTY BY OCULUS OF THE ACCURACY, SAFETY, OR USEFULNESS FOR ANY PURPOSE OF ANY INTELLECTUAL PROPERTY AT ANY TIME MADE AVAILABLE TO RUTHIGEN.

**Article XIII**  
**Indemnification**

13.1 **Indemnification by Ruthigen**. Subject to Section 13.3, Ruthigen hereby agrees to indemnify, save, defend and hold Oculus, its Affiliates, and each of their respective officers, directors, consultants, agents and employees harmless (collectively, "**Oculus Indemnitees**") from and against any and all Third Party suits, claims, actions, demands, liabilities, expenses, and/or losses, including reasonable legal expenses and attorneys' fees (collectively, "**Losses**" and each a "**Loss**") alleged against any of the Oculus Indemnitees, to the extent resulting from or arising out of (i) Ruthigen's or its Affiliates' or sublicensees' (if applicable) Development, Commercialization or Manufacture (as applicable) of the Product in the Field in the Territory, except to the extent such Losses result from or arise out of (x) the inaccuracy of any representation of Oculus set forth in this Agreement; (y) the breach of any warranty or covenant contained in this Agreement by Oculus; or (z) the negligence or willful misconduct of Oculus; (ii) the inaccuracy of any representation of Ruthigen set forth in this Agreement; (iii) the breach of any warranty or covenant contained in this Agreement by Ruthigen; or (iv) the negligence or willful misconduct of Ruthigen.

13.2 **Indemnification by Oculus**. Oculus hereby agrees to indemnify, save, defend and hold Ruthigen, its Affiliates, their respective sublicensees, and each of their respective officers, directors, consultants, agents, and employees (collectively, "**Ruthigen Indemnitees**") harmless from and against any and all Third Party Losses resulting from or arising out of (i) the inaccuracy of any representation of Oculus set forth in this Agreement; (ii) the breach of any warranty or covenant contained in this Agreement by Oculus; or (iii) the negligence or willful misconduct of Oculus.

13.3 **Indemnification Process**. Each indemnified Party agrees to give the indemnifying Party prompt written notice of any Loss or discovery of fact upon which such indemnified Party intends to base a request for indemnification under Sections 13.1 or 13.2. Each Party shall furnish promptly to the other copies of all papers and official documents received in respect of any Loss. With respect to any Loss relating solely to the payment of money damages and which will not result in the indemnified Party becoming subject to injunctive or other relief or otherwise adversely affecting the business of the indemnified Party in any manner, and as to which the indemnifying Party shall have acknowledged in writing the obligation to indemnify the indemnified Party hereunder, the indemnifying Party shall have the sole right to defend, settle, or otherwise dispose of such Loss, on such terms as the indemnifying Party, in its sole discretion, shall deem appropriate. The indemnifying Party shall obtain the written consent of the indemnified Party, which shall not be unreasonably withheld or delayed, prior to ceasing to defend, settling or otherwise disposing of any Loss if as a result thereof the indemnified Party would become subject to injunctive or other equitable relief or any remedy other than the payment of money, which payment would be the responsibility of the indemnifying Party. The indemnifying Party shall not be liable for any settlement or other disposition of a Loss by the indemnified Party which is reached without the written consent of the indemnifying Party.

13.4 **Insurance**. Ruthigen agrees to obtain and maintain in effect a policy or policies of insurance relating to its Development and Commercialization of Products hereunder and under the Shared Services Agreement. Such policies shall be issued by one or more reputable insurers, and shall contain reasonable terms of coverage in light of the obligations set forth above. Ruthigen undertakes to obtain and maintain in effect a policy or policies of insurance covering during the Clinical Development of the Product a minimum of \$3 Million per single damage, and during the Commercialization of the Product a minimum of \$10 Million per single damage. Upon the request of Oculus, Ruthigen shall provide evidence of insurance coverage in compliance with this Section to Oculus.

13.5 This Article XIII shall survive the termination or expiration of this Agreement.

**Article XIV**  
**Term and Termination**

14.1 Term. This Agreement shall commence as of the Effective Date and, unless sooner terminated as provided herein, shall continue in effect until terminated as provided herein.

14.2 Termination.

(a) Material failure of Ruthigen or Oculus to comply with any of their respective material obligations contained in this Agreement which constitutes a material breach shall entitle the other Party to give the Party a default notice describing such breach in detail and requiring it to cure such default. If such default is not cured within ninety (90) days after receipt of such notice, the notifying Party shall be entitled (without prejudice to any of its other rights conferred on it by this Agreement) to terminate this Agreement. Notwithstanding the foregoing, in the event of a non-monetary default, if the default is not reasonably capable of being cured within the ninety (90)-day cure period by the defaulting Party and such defaulting Party is making a good faith effort to cure such default, the notifying Party may not terminate this Agreement, provided however, that the notifying Party may terminate this Agreement if such default is not cured within one hundred twenty (120) days of such original notice of default. The right of either Party to terminate this Agreement as herein above provided shall not be affected in any way by its waiver of, or failure to take action with respect to any previous default.

(b) In the event that one of the Parties hereto shall go into liquidation, a receiver or a trustee may be appointed for the property or estate of that Party and said receiver or trustee is not removed within one hundred twenty (120) days, or the Party makes an assignment for the benefit of creditors, and whether any of the aforesaid bankruptcy events be the outcome of the voluntary act of that Party, or otherwise, the other Party shall be entitled to terminate this Agreement.

(c) In the event that this Agreement is terminated by either Party in accordance with Sections 14.2(a) or (b) hereof, Ruthigen will: (i) deliver to Oculus the Oculus Know-How and assign to Oculus its rights in said Oculus Know-How and Oculus Patents and Joint Patents; (ii) not use the Oculus Know-How as long as it has to be kept confidential pursuant to Article X hereof; (iii) make all payments accrued under this Agreement prior to the effective termination date; (iv) transfer all regulatory filings and approvals, designations and exclusivity related to the Product, to Oculus upon Oculus's written request for same; and (v) at its discretion, offer to sell Ruthigen's inventory of Product and Substances either to Oculus pursuant to the terms of subsection (d) below or sell its inventory of Products as of the effective date of termination to Third Parties (subject to its obligation to make royalty payment).

(d) If Ruthigen has terminated the Agreement pursuant to Section 14.2(a) above, Ruthigen may offer to sell to Oculus, at any time within ninety (90) days of such termination, all or any portion of the inventory of the Substance and/or the Product owned by Ruthigen or its Affiliates which are intended for sale in the Territory at a price equal to Ruthigen's or its Affiliate's fully burdened costs for such inventory, and Oculus may purchase all or any portion of the inventory at Oculus's election. Such election shall be made by Oculus in writing in a notice to Ruthigen, within thirty (30) days of such termination. If Oculus purchases such Ruthigen inventory, Ruthigen shall ship at Oculus's cost and direction such inventory to Oculus. Oculus shall pay for such inventory in advance of receipt of such inventory.

(e) If Oculus has terminated the Agreement pursuant to Section 14.2(a) above, Ruthigen may offer to sell to Oculus, at any time within ninety (90) days of such termination, all or any portion of Ruthigen's inventory of Manufacturing Equipment purchased from Oculus, and Oculus may purchase all or any portion of the inventory at Oculus's election. Such election shall be made by Oculus in writing in a notice to Ruthigen, within thirty (30) days of such termination. If Oculus purchases such Ruthigen inventory of Manufacturing Equipment, Ruthigen shall ship at Oculus's cost and direction such inventory to Oculus. Oculus shall pay for such inventory in advance of receipt of such inventory.

(f) Except where expressly provided for otherwise in this Agreement, termination or expiration of this Agreement shall not relieve the Parties hereto of any liability, including any obligation to make payments hereunder, which accrued hereunder prior to the effective date of such termination or expiration, nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement nor prejudice any Party's right to obtain performance of any obligation.

14.3 Surviving Rights. The rights and obligations set forth in this Agreement shall extend beyond the termination of the Agreement only to the extent expressly provided for herein as follows: Article I, Sections 6.13(d) and 6.14, Article IX, Article X, the definitions in Article XI, Sections 11.3, 11.5, 12.2, Article XIII, Sections 14.2(c) – (f) and 14.3, and Article XV.

14.4 Notwithstanding anything to the contrary in this Article XIV, neither Party may terminate this Agreement pursuant to Section 14.2(a) if the other Party has delivered a notice of dispute resolution under Section 15.10, and the Parties shall continue to perform this Agreement during the period of such dispute resolution and during the period of any subsequently instituted arbitration proceeding.

**Article XV**  
**Miscellaneous**

15.1 Assignment.

(a) Each Party may assign this Agreement in its entirety upon notice to the other Party to any of its Affiliates or to a successor to all or substantially all of such Party's business or assets; provided, however, that such assignment shall not relieve such Party of its responsibilities for performance of its obligations under this Agreement. Except as provided herein, neither Party to this Agreement shall have the right to assign its rights or obligations under this Agreement.

(b) This Agreement shall be binding upon and inure to the benefit of the permitted assigns of the Parties. Any purported assignment not in accordance with this Agreement shall be void.

15.2 Force Majeure. Neither Party shall lose any rights hereunder or be liable to the other Party for damages or losses on account of failure of performance by the defaulting Party if the failure is occasioned by war, fire, explosion, flood, strike, lockout, embargo, act of God, or any other cause beyond the reasonable control of the defaulting Party, provided that the Party claiming force majeure has extended reasonable efforts to avoid or remedy any such force majeure, continues to employ such efforts and promptly notifies the other Party of such force majeure event.

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

15.4 No Trademark Rights. No right, express or implied, is granted by this Agreement to use in any manner the names "Ruthigen" or "Oculus" or any other trade name or trademark of the other Party or its Affiliates in connection with the performance of this Agreement.

15.5 Notices. All notices and consents hereunder shall be in writing, effective upon receipt, and shall be delivered personally, mailed by registered or certified mail (return receipt requested, postage prepaid), or sent by express courier service, to the other Party at the following addresses (or at such other address for a Party as shall be specified by like notice):

(a) If to Ruthigen:

RUTHIGEN, INC.  
2455 Bennett Valley Road, Suite C116  
Santa Rosa, CA 95404  
Attn: CFO

(b) If to Oculus:

OCULUS INNOVATIVE SCIENCES, INC.  
1129 N. McDowell  
Petaluma, CA 94954  
Attn: CFO

15.6 Waiver. Except as specifically provided herein, the waiver from time to time by either of the Parties of any of their rights or their failure to exercise any right or remedy must be in a signed writing to be effective, shall not operate or be construed as a continuing waiver of same or of any other of such Party's rights or remedies provided in this Agreement.

15.7 Severability. Each Party hereby agrees that it does not intend, by its execution hereof, to violate any public policies, statutory or common laws, rules, regulations, treaties or decisions of any government agency or executive body thereof of any country or community or association of countries. Should one or more provisions of this Agreement be or become invalid, such provision shall be severed from this Agreement and the Parties hereto shall use good faith efforts to substitute, by mutual consent, valid provisions for such invalid provisions, which valid provisions in their economic and other effects are sufficiently similar to the invalid provisions that it can be reasonably assumed that the Parties would have entered into this Agreement with such valid provisions. In case such valid provisions cannot be agreed upon, the invalidity of one or several provisions of this Agreement shall not affect the validity of this Agreement as a whole or the validity of any portions hereof, unless the invalid provisions are of such essential importance to this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without the invalid provision.

15.8 Ambiguities. The Parties acknowledge and agree that: (a) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; (b) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (c) the terms and provisions of this Agreement shall be construed fairly as to the Parties hereto and not in favor of or against any Party, regardless of which Party was generally responsible for the preparation of this Agreement.

15.9 Governing Law. This Agreement shall be governed by and construed in accordance with the laws in force in the State of California, without giving effect to the choice of laws provisions thereof.

#### 15.10 Dispute Resolution.

(a) In the event that any dispute should arise between the Parties hereto with respect to any matter covered by this Agreement or the interpretation of this Agreement (except for an Audit Disagreement, which shall be governed by Section 8.7(b)), the Parties hereto shall resolve such dispute in accordance with the procedures set forth in this Section 15.10.

(b) In the event of a dispute of the nature specified in Section 15.10(c), prior to initiating arbitration as set forth in Section 15.10(c), either Party may request that the Chief Executive Officer of each Party meet in an effort to resolve the dispute amicably. In the event of such a request, the Parties shall arrange for such a meeting to be held within 30 days of the request at which the Chief Executive Officers shall seek to resolve the dispute. If the Chief Executive Officers are unable to resolve the dispute at such meeting, or if the meeting does not occur for any reason within 30 days after the date of the request, either party may proceed to initiate an arbitration to resolve the dispute as set forth in Section 15.10(c).

(c) (i) Subject to Section 15.10(b), each Party may submit any matter referred to in Section 15.10(a), other than matters affecting the validity or enforceability of Patents (which matters shall not be arbitrated) to arbitration by notifying the other Party, in writing, of such dispute. Within 30 days after receipt of such notice, the Parties shall designate in writing one arbitrator to resolve the dispute; provided that, if the Parties cannot agree on an arbitrator within such 30-day period, the arbitrator shall be selected by the San Francisco, CA, Office of the American Arbitration Association. The arbitrator shall be a retired federal or state judge and have significant expertise in trying or arbitrating patent license agreements, and shall not be an Affiliate, Representative or stockholder of any party hereto. If neither the Parties nor the San Francisco Office of the American Arbitration Association is able to identify an individual to serve as the arbitrator, the San Francisco Office of the American Arbitration Association shall select a single arbitrator from the CPC Panel of Distinguished Neutrals of the CPR Institute for Dispute Resolution.

(ii) Within 30 days after the designation of the arbitrator, the arbitrator and the Parties shall meet, at which time the Parties shall be required to set forth in writing all disputed issues and a proposed ruling on the merits of each such issue.

(iii) The arbitrator shall set a date for a hearing, which shall be no later than 45 days after the submission of written proposals pursuant to Section 15.10(c)(ii), to discuss each of the issues identified by the Parties. Each Party hereto shall have the right to be represented by counsel. Except as provided herein, the arbitration shall be governed by the Commercial Arbitration Rules of the American Arbitration Association; provided, however, that the Federal Rules of Evidence shall apply with regard to the admissibility of evidence and the arbitration shall be conducted by a single arbitrator.

(iv) The arbitrator shall use his or her reasonable efforts to rule on each disputed issue within 30 days after the completion of the hearings described in Section 15.10(c)(iii). The determination of the arbitrator as to the resolution of any dispute shall be binding and conclusive upon the Parties. All rulings of the arbitrator shall be in writing and shall be delivered to the Parties.

(v) The (1) attorneys' fees of the parties hereto in any arbitration, (2) fees of the arbitrator and (3) costs and expenses of the arbitration shall be borne by the Party that shall not have prevailed in the arbitration as determined by the arbitrator.

(vi) Any arbitration pursuant to this Section 15.10 shall be conducted in San Francisco, California. Any arbitration award may be entered in and enforced by any court having jurisdiction thereover and shall be final and binding upon the Parties hereto.

(vii) Notwithstanding the foregoing, nothing in this Section 15.10 shall be construed as limiting in any way the right of a Party hereto to seek a temporary restraining order or other injunctive or equitable relief with respect to any actual or threatened breach of this Agreement from a court of competent jurisdiction. Should any Party to this Agreement seek a temporary restraining order or other injunctive relief, then for purposes of determining whether to grant such temporary restraining order or other injunctive relief, the dispute underlying the request for such temporary restraining order or other injunctive relief may be heard by such court of competent jurisdiction.

15.11 Headings. The Section and Paragraph headings contained herein are for the purposes of convenience only and are not intended to define or limit the contents of said Sections or Paragraphs.

15.12 Counterparts. This Agreement may be executed by the Parties in one or more counterparts. Such counterparts may be exchanged by facsimile (provided that each executed counterpart is transmitted in one complete transmission). Where there is an exchange of executed counterparts, each Party shall be bound by this Agreement notwithstanding that original copies of this Agreement may not be exchanged immediately. The Parties shall cooperate after execution of this Agreement and exchange by facsimile to ensure that each Party obtains an original, executed copy of this Agreement.

15.13 Entire Agreement; Amendments. This Agreement, including all Exhibits attached hereto supersede and terminate all prior agreements and understandings between the Parties with respect to the subject matter hereof. No subsequent alteration, amendment, change, or addition to this Agreement shall be binding upon the Parties hereto unless reduced to writing and signed by the respective authorized officers of the Parties. For so long as the Parties are members of the same Consolidated Group, any amendment to this Agreement shall be subject to prior written approval of the Board of Directors of each of the Parties in compliance with the provisions of Section 144 of the Delaware and Nevada General Corporation Law.

15.14 Expenses. Except as otherwise specified in this Agreement, all costs and expenses, including, without limitation, fees and disbursements of counsel, financial advisers, and accountants, incurred in connection with this Agreement and the transactions contemplated hereby shall be paid by the Party incurring such costs and expenses.

15.15 Independent Contractors. The status of the Parties under this Agreement shall be that of independent contractors. Neither Party shall have the right to enter into any agreements on behalf of the other Party, nor shall it represent to any person that it has any such right or authority. Nothing in this Agreement shall be construed as establishing a partnership or joint venture relationship between the Parties.

15.16 Limitation of Liability. TO THE MAXIMUM EXTENT PERMITTED UNDER APPLICABLE LAW, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY OR ANY OF ITS AFFILIATES FOR ANY INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES, INCLUDING, WITHOUT LIMITATION, LOST PROFITS OR LOST REVENUES, WHETHER UNDER ANY CONTRACT, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY. This limitation of liability shall not apply to damages caused by infringement of Patents, a breach of Section 2.1 (License), a breach of Section 2.4 (Non-Compete), a breach of Article X (Confidentiality), or amounts owed to Third Parties pursuant to a Party's indemnification obligation in Article XIII.

[SIGNATURES ON FOLLOWING PAGE]

IN WITNESS WHEREOF, Ruthigen and Oculus have caused this Agreement to be executed as of May 23, 2013 by their respective duly authorized representatives.

**OCULUS**

**RUTHIGEN**

**OCULUS INNOVATIVE SCIENCES INC.**

**RUTHIGEN, INC.**

By: /s/ Jim Schutz

By: /s/ Hojabr Alimi

Name: Jim Schutz

Name: Hojabr Alimi

Title: CEO

Title: CEO

Date: 22 May 2013

Date: 23 May 2013

**Schedules:**

List of Oculus Patents

Specifications of Product and Substance

Development and Commercialization Plan



**Schedule 1**

## PATENTS

Country	Application Number	Publication Number	Patent No.	Title
EP	00 124 968.9	1 103 264 A2	EP 1 103 264 B1	Active oxygen containing solution for promoting growth of tissue cells at wound sites
US	09/714,826			Solution for promoting growth of tissue cells at wound sites and production process therefor
US	10/146,140	2002/0160053 A1		Solution for promoting growth of tissue cells at wound sites and production process therefore
US	60/338,376			Negative and positive oxidative reductive potential (ORP) water and method and apparatus for producing the same
PCT	PCT/US02/38861	WO 03/048421 A1		Method and apparatus for producing negative and positive oxidative reductive potential (ORP) water
AU	2002353060	AU2002353060 A1		Method and apparatus for producing negative and positive oxidative reductive potential (ORP) water
CA	2,468,856	CA2468856 A1	2,468,856 C	Method and apparatus for producing negative and positive oxidative reductive potential (ORP) water
JP	549596/2003	511280/2005	JP 3988827 B2	Method and apparatus for producing negative and positive oxidative reductive potential (ORP) water
EP	02790029.9	1 461 474 A1	EP 1 461 474 B1	Method and apparatus for producing negative and positive oxidative reductive potential (ORP) water
AT	AT 2002-0790029T	AT 535262 T		Method and apparatus for producing negative and positive oxidative reductive potential (ORP) water
ES	ES 20020790029T	ES 2377945 T3		Method and apparatus for producing negative and positive oxidative reductive potential (ORP) water
US	10/496,092	2005/0121334 A1	8,062,500 B2	Method and apparatus for producing negative and positive oxidative reductive potential (ORP) water
MX	PA/a/2003/007923	MX PA03007923A		Method and apparatus for producing negative and positive oxidative reductive potential (ORP) water
AU	2009-203008	AU2009203008 A1		Method and apparatus for producing negative and positive oxidative reductive potential (ORP) water
AU	2012201437		2012201437	Method and apparatus for producing negative and positive oxidative reductive potential (ORP) water
US	10/242,779	2003/0056805 A1	7,090,753 B2	Electrolytic cell for producing charged anode water suitable for surface cleaning or treatment, and method for producing same and use of the same
US	11/502,821	2006/0272954 A1	7,442,288 B2	Electrolytic cell for producing charged anode water suitable for surface cleaning or treatment, and method for producing same and use of the same

EP	02020429.3	EP 1 293 481 A2/ EP 1 293 481 A3	EP 1 293 481 B1	Electrolytic cell for producing charged anode water suitable for surface cleaning or treatment, and method for producing same and use of the same
AT	20020020429T	AT 354543 T		Electrolytic cell for producing charged anode water suitable for surface cleaning or treatment, and method for producing same and use of the same
DE	20020020429T	DE 1293481 T1		Electrolytic cell for producing charged anode water suitable for surface cleaning or treatment, and method for producing same and use of the same
DE	20026018256T	DE 60218256 T2		Electrolytic cell for producing charged anode water suitable for surface cleaning or treatment, and method for producing same and use of the same
ES	20020020429T	ES 2277979 T3		Electrolytic cell for producing charged anode water suitable for surface cleaning or treatment, and method for producing same and use of the same
US	60/533,583			Oxidative potential water solution, processes for producing same and methods of using the same
US	10/862,092	2005/0139808		Oxidative potential water solution, processes for producing same and methods of using the same
US	10/916,278	2005/0196462 A1		Oxidative potential water solution, processes for producing same and methods of using the same
US	10/916,566	2005/0142157 A1		Oxidative potential water solution, processes for producing same and methods of using the same
PCT	PCT/US04/043961	WO 05/065383 A1		Oxidative potential water solution, processes for producing same and methods of using the same
CN	200480002201	CN1845877A		Oxidative potential water solution, processes for producing same and methods of using the same
JP	547576/2006	2007-517064		Oxidative potential water solution, processes for producing same and methods of using the same
KR	10-2006-7015435			Oxidative potential water solution, processes for producing same and methods of using the same
IN	4188/DELNP/2005		249157	Oxidative potential water solution, processes for producing same and methods of using the same
MX	PA/a/2005/009960			Oxidative potential water solution, processes for producing same and methods of using the same
CA	2,553,943			Oxidative potential water solution, processes for producing same and methods of using the same
AU	2004311432			Oxidative potential water solution, processes for producing same and methods of using the same
AU	2011200390			Oxidative potential water solution, processes for producing same and methods of using the same
EP	04815950.3	EP 1 702 161 A2		Oxidative potential water solution, processes for producing same and methods of using the same

EP	10012683.8	EP 2 330 081 A2/ EP 2 330 081 A3		Oxidative potential water solution, processes for producing same and methods of using the same
HK	07103435.0	1096372A		Oxidative potential water solution, processes for producing same and methods of using the same
US	60/664,361			Method of treating diabetic foot ulcers using oxidative reductive potential water solution
US	60/730,743			Method of treating diabetic foot ulcers using oxidative reductive potential water solution
US	60/760,557			Method of treating diabetic foot ulcers using oxidative reductive potential water solution
US	11/388,912	2006/0235350 A1	8,323,252	Method of treating diabetic foot ulcers using oxidative reductive potential water solution
PCT	PCT/US06/11252	WO 2006/102681		Method of treating diabetic foot ulcers using oxidative reductive potential water solution
EP	06739816.4	1 863 502 A1		Method of treating diabetic foot ulcers using oxidative reductive potential water solution
CN	200680013613.2			Method of treating diabetic foot ulcers using oxidative reductive potential water solution
IN	8161/DELNP/2007			Method of treating diabetic foot ulcers using oxidative reductive potential water solution
KR	10-2007-7024246			Method of treating diabetic foot ulcers using oxidative reductive potential water solution
JP	503291/2008	534517/2008		Method of treating diabetic foot ulcers using oxidative reductive potential water solution
CA	2,602,522			Method of treating diabetic foot ulcers using oxidative reductive potential water solution
AU	2006226750		2006226750	Method of treating diabetic foot ulcers using oxidative reductive potential water solution
MX	MX/a/2007/011709		304153	Method of treating diabetic foot ulcers using oxidative reductive potential water solution
BR	PI0609429-5			Method of treating diabetic foot ulcers using oxidative reductive potential water solution
HK	08106473.5			Method of treating diabetic foot ulcers using oxidative reductive potential water solution
HK	08106484.2			Method of treating diabetic foot ulcers using oxidative reductive potential water solution
HK	08106689.5	1116342 A		Method of treating diabetic foot ulcers using oxidative reductive potential water solution
US	60/667,101			Method of Treating Second and Third Degree Burns Using Oxidative Reductive Potential Water
US	11/388,930	2006/0241546 A1		Method of Treating Second and Third Degree Burns Using Oxidative Reductive Potential Water
PCT	PCT/US06/11251	WO 2006/102680		Method of Treating Second and Third Degree Burns Using Oxidative Reductive Potential Water
EP	06739815.6	EP 1 863 501 A2		Method of Treating Second and Third Degree Burns Using Oxidative Reductive Potential Water
CN	200680013725.8		101163492 B	Method of Treating Second and Third Degree Burns Using Oxidative Reductive Potential Water
IN	8160/DELNP/2007			Method of Treating Second and Third Degree Burns Using Oxidative Reductive Potential Water
KR	10-2007-7024245			Method of Treating Second and Third Degree Burns Using Oxidative Reductive Potential Water

JP	503290/2008	534516/2008		Method of Treating Second and Third Degree Burns Using Oxidative Reductive Potential Water
CA	2,602,411			Method of Treating Second and Third Degree Burns Using Oxidative Reductive Potential Water
AU	2006226749		2006226749	Method of Treating Second and Third Degree Burns Using Oxidative Reductive Potential Water
MX	MX/a/2007/011706		304152	Method of Treating Second and Third Degree Burns Using Oxidative Reductive Potential Water
BR	PI 0609711-1			Method of Treating Second and Third Degree Burns Using Oxidative Reductive Potential Water
HK	08106681.3	1116340A		Method of Treating Second and Third Degree Burns Using Oxidative Reductive Potential Water
US	60/676,883			Method of using oxidative reductive potential water solution in dental applications
US	11/416,091	2006/0253060 A1		Method of using oxidative reductive potential water solution in dental applications
PCT	PCT/US06/16856	WO 2006/119300		Method of using oxidative reductive potential water solution in dental applications
EP	06752104.7	EP 1 896 043 A2		Method of using oxidative reductive potential water solution in dental applications
CN	200680019804.X			Method of using oxidative reductive potential water solution in dental applications
IN	9318/DELNP/2007			Method of using oxidative reductive potential water solution in dental applications
BR	PI0610901-2			Method of using oxidative reductive potential water solution in dental applications
CA	2,606,734			Method of using oxidative reductive potential water solution in dental applications
MX	MX/a/2007/013774			Method of using oxidative reductive potential water solution in dental applications
JP	510139/2008	540430/2008		Method of using oxidative reductive potential water solution in dental applications
KR	10-2007-7028020			Method of using oxidative reductive potential water solution in dental applications
AU	2006242175			Method of using oxidative reductive potential water solution in dental applications
HK	08113022.7	1123484A		Method of using oxidative reductive potential water solution in dental applications
AU	2012241151			Method of using oxidative reductive potential water solution in dental applications
US	60/760,635			Methods of treating or preventing peritonitis with oxidative reductive potential water solution
US	11/656,328	2007/0173755	US 8,147,444	Methods of treating or preventing peritonitis with oxidative reductive potential water solution
PCT	PCT/US07/060860	WO 2007/085021		Methods of treating or preventing peritonitis with oxidative reductive potential water solution

EP	07717981.0	EP 1 993 570 A2		Methods of treating or preventing peritonitis with oxidative reductive potential water solution
CN	200780009873.7	CN 101405013A		Methods of treating or preventing peritonitis with oxidative reductive potential water solution
IN	7025/DELNP/2008			Methods of treating or preventing peritonitis with oxidative reductive potential water solution
KR	10-2008-7020291			Methods of treating or preventing peritonitis with oxidative reductive potential water solution
JP	551573/2008	523832/2009		Methods of treating or preventing peritonitis with oxidative reductive potential water solution
CA	2,637,197			Methods of treating or preventing peritonitis with oxidative reductive potential water solution
MX	MX/a/2008/009302			Methods of treating or preventing peritonitis with oxidative reductive potential water solution
BR	07006676-7			Methods of treating or preventing peritonitis with oxidative reductive potential water solution
AU	2007205863			Methods of treating or preventing peritonitis with oxidative reductive potential water solution
HK	09108793.3	1130673A		Methods of treating or preventing peritonitis with oxidative reductive potential water solution
US	13/436,288	2012/0251631 A1		Methods of treating or preventing peritonitis with oxidative reductive potential water solution
US	60/760,567			Methods of preventing or treating sinusitis with oxidative reductive potential water solution
US	11/656,088	2007/0196434		Methods of preventing or treating sinusitis with oxidative reductive potential water solution
PCT	PCT/US07/060856	WO 2007/085019 A2		Methods of preventing or treating sinusitis with oxidative reductive potential water solution
EP	07718192.3	EP 1 993 572 A2		Methods of preventing or treating sinusitis with oxidative reductive potential water solution
CN	200780009773.4	CN 101405011A		Methods of preventing or treating sinusitis with oxidative reductive potential water solution
IN	7024/DELNP/2008			Methods of preventing or treating sinusitis with oxidative reductive potential water solution
KR	10-2008-7020289			Methods of preventing or treating sinusitis with oxidative reductive potential water solution
JP	551571/2008	523830/2009		Methods of preventing or treating sinusitis with oxidative reductive potential water solution
CA	2,637,178			Methods of preventing or treating sinusitis with oxidative reductive potential water solution
MX	MX/a/2008/009234			Methods of preventing or treating sinusitis with oxidative reductive potential water solution

BR	PI0706677-5			Methods of preventing or treating sinusitis with oxidative reductive potential water solution
AU	2007205861			Methods of preventing or treating sinusitis with oxidative reductive potential water solution
HK	09108882.5	1130683A		Methods of preventing or treating sinusitis with oxidative reductive potential water solution
US	60/760,645			Methods of Treating Inflammation and Hypersensitivity With Oxidative Reductive Potential Water Solution
US	11/656,087	2007/0196357 A1		Methods of Treating Inflammation and Hypersensitivity With Oxidative Reductive Potential Water Solution
PCT	PCT/US07/060854	WO 2007/085018 A2		Methods of Treating Inflammation and Hypersensitivity With Oxidative Reductive Potential Water Solution
EP	07718160.0	EP 1 993 571 A2		Methods of Treating Inflammation and Hypersensitivity With Oxidative Reductive Potential Water Solution
CN	200780009789.5	CN 101405012A		Methods of Treating Inflammation and Hypersensitivity With Oxidative Reductive Potential Water Solution
IN	7023/DELNP/2008			Methods of Treating Inflammation and Hypersensitivity With Oxidative Reductive Potential Water Solution
KR	10-2008-7020287			Methods of Treating Inflammation and Hypersensitivity With Oxidative Reductive Potential Water Solution
JP	551570/2008	523829/2009		Methods of Treating Inflammation and Hypersensitivity With Oxidative Reductive Potential Water Solution
CA	2,637,175			Methods of Treating Inflammation and Hypersensitivity With Oxidative Reductive Potential Water Solution
MX	MX/a/2008/009235			Methods of Treating Inflammation and Hypersensitivity With Oxidative Reductive Potential Water Solution
BR	PI0706671-6			Methods of Treating Inflammation and Hypersensitivity With Oxidative Reductive Potential Water Solution
AU	2007205860			Methods of Treating Inflammation and Hypersensitivity With Oxidative Reductive Potential Water Solution
HK	09108800.4	1130675A		Methods of Treating Inflammation and Hypersensitivity With Oxidative Reductive Potential Water Solution
US	12/643,191	2010/092399 A1		Methods of Treating Inflammation and Hypersensitivity With Oxidative Reductive Potential Water Solution
US	61/139,972			Methods of Treating or Preventing Biofilm Associated Infections with Free Available Chlorine Water
US	12/645,419	2010/166809 A1		Methods of Treating or Preventing Biofilm Associated Infections with Free Available Chlorine Water
PCT	PCT/US09/69345			Methods of Treating or Preventing Biofilm Associated Infections with Free Available Chlorine Water
US				Methods of Treating or Preventing Biofilm Associated Infections with Free Available Chlorine Water

EP	09796575.0	EP 2 376 093 A2		Methods of Treating or Preventing Biofilm Associated Infections with Free Available Chlorine Water
US	61/177,275			Methods of Treating or Preventing Influenza Associated Illnesses with Oxidative Reductive Potential Water Solutions
PCT	PCT/US10/34238			Methods of Treating or Preventing Influenza Associated Illnesses with Oxidative Reductive Potential Water Solutions
US	13/320,225	2012/0207853 A1		Methods of Treating or Preventing Influenza Associated Illnesses with Oxidative Reductive Potential Water Solutions
CN	201080027346.0	CN102481357A		Methods of Treating or Preventing Influenza Associated Illnesses with Oxidative Reductive Potential Water Solutions
CA				Methods of Treating or Preventing Influenza Associated Illnesses with Oxidative Reductive Potential Water Solutions
EP	10775333.7	EP 2 429 578 A1		Methods of Treating or Preventing Influenza Associated Illnesses with Oxidative Reductive Potential Water Solutions
IN	9597/DELNP/2011			Methods of Treating or Preventing Influenza Associated Illnesses with Oxidative Reductive Potential Water Solutions
MX	MX/A/2011/013296			Methods of Treating or Preventing Influenza Associated Illnesses with Oxidative Reductive Potential Water Solutions
AU	2010247866			Methods of Treating or Preventing Influenza Associated Illnesses with Oxidative Reductive Potential Water Solutions
US	60/906,939			Antimicrobial solutions containing dichloride monoxide and methods of making and using the same
PCT	PCT/US08/56919	WO 2008/112940 A1		Antimicrobial solutions containing dichloride monoxide and methods of making and using the same
EP	08732167.5	EP 2 136 819 A1		Antimicrobial solutions containing dichloride monoxide and methods of making and using the same
CN	200880013108.7	101932330A		Antimicrobial solutions containing dichloride monoxide and methods of making and using the same
HK	10106353.6	1140138A		Antimicrobial solutions containing dichloride monoxide and methods of making and using the same
IN	5841/DELNP/2009			Antimicrobial solutions containing dichloride monoxide and methods of making and using the same
JP	553790/2009	521489/2010		Antimicrobial solutions containing dichloride monoxide and methods of making and using the same
KR	10-2009-7020066			Antimicrobial solutions containing dichloride monoxide and methods of making and using the same
AU	2008224968			Antimicrobial solutions containing dichloride monoxide and methods of making and using the same
BR	PI0808856-0			Antimicrobial solutions containing dichloride monoxide and methods of making and using the same
MX	MX/a/2009/009760			Antimicrobial solutions containing dichloride monoxide and methods of making and using the same

CA	2,680,483			Antimicrobial solutions containing dichloride monoxide and methods of making and using the same
US	12/531,276	2010/0112092 A1		Antimicrobial solutions containing dichloride monoxide and methods of making and using the same
US	61/058,208			Method and Apparatus for Treating a Wound
US	12/477,792	2010/0106079 A1		Method and Apparatus for Treating a Wound
PCT	PCT/US2009/046168	WO 2009/149208 A2		Method and Apparatus for Treating a Wound
US	61/268,764			Solution Containing Hypochlorous Acid and Methods of Using Same
PCT	PCT/US10/38697			Solution Containing Hypochlorous Acid and Methods of Using Same
US	13/378,659	2012/0269904 A1		Solution Containing Hypochlorous Acid and Methods of Using Same
CN	201080033620.5	CN102480972A		Solution Containing Hypochlorous Acid and Methods of Using Same
BR	PI10118861			Solution Containing Hypochlorous Acid and Methods of Using Same
MX	MX/A/2011/013682			Solution Containing Hypochlorous Acid and Methods of Using Same
KR	10-2012-7000196			Solution Containing Hypochlorous Acid and Methods of Using Same
JP	516208/2012	530142/2012		Solution Containing Hypochlorous Acid and Methods of Using Same
CA	CA 2,765,696			Solution Containing Hypochlorous Acid and Methods of Using Same
US	61/230,023			Hydrogel Formulation Comprising Oxidative Reductive Potential Water
PCT	PCT/US2010/043978	WO2011014809 A1		Hydrogel Formulation Comprising Oxidative Reductive Potential Water
US	13/387,923	2012/0164235 A1		Hydrogel Formulation Comprising Oxidative Reductive Potential Water
CN	201080039873.3	102596207 A		Hydrogel Formulation Comprising Oxidative Reductive Potential Water
BR	PI1200689.1			Hydrogel Formulation Comprising Oxidative Reductive Potential Water
MX	MX/A/2012/001415			Hydrogel Formulation Comprising Oxidative Reductive Potential Water



CA	2,769,644	CA 2769644 A1		Hydrogel Formulation Comprising Oxidative Reductive Potential Water
AU	2010278812			Hydrogel Formulation Comprising Oxidative Reductive Potential Water
EP	EP 10805132.7	EP 2 459 201 A1		Hydrogel Formulation Comprising Oxidative Reductive Potential Water
HK	12112598.7			Hydrogel Formulation Comprising Oxidative Reductive Potential Water
US	61/680,769			Methods of treating polycystic ovarian syndrome using chlorogenic acid
JP	03-215471 08/27/1991	05-339769	3236315 09/28/2001	
JP	03-346494 12/27/1991	07-000966	3247134 10/02/2001	
JP	08/27/91		3299250 04/19/2002	
JP	12/27/2001		3338435 08/09/2002	
JP	06/21/1994		3396853 04/14/2003	
JP	12/28/1993		3458341 08/08/2003	
JP	09-318775 11-151493 11/19/1997		3952228 05/11/2007	
JP	2000-003647 01/12/2000	2001-191076	4462513 02/26/2010	
JP	08-292519 11/05/1996	10-128331 05/19/1998		

Schedule 2

SPECIFICATIONS

**6.0 CHEMISTRY, MANUFACTURING AND CONTROLS**

**6.1 Drug Substance**

Hypochlorous acid ([ ]\*) is the active pharmaceutical ingredient of RUT100-05 surgical rinse solution at a concentration in the drug product of [ ]\*. This optimized formulation was based on RUT058-60. The molecular formula and relative molecular weight of hypochlorous acid are HOCl and 52.46, respectively. Hypochlorous acid is fully miscible in water and [ ]\* a [ ]\*. The [ ]\* in [ ]\* such as the [ ]\* is [ ]\* ([ ]\* ([ ]\*) [ ]\*, [ ]\*).

The [ ]\* is [ ]\* the [ ]\*. [ ]\*, when [ ]\* to the [ ]\*, [ ]\* as [ ]\* of the [ ]\* to [ ]\*: [ ]\*

[ ]\* of [ ]\* is [ ]\* the [ ]\* with [ ]\* throughout the [ ]\*.

**6.2 Components and Composition Finished Dosage Form**

Tables 6.2.1 and 6.2.2 provide the qualitative and quantitative description of the components and composition of the RUT100-05 surgical rinse finished drug product.

Table 6.2.1 Investigational New Drug Product Composition

Formulation Component	Manufacturer	Function	Concentration (mg/L)
[ ]*	[ ]*	[ ]*	[ ]* <sup>1</sup>
[ ]*	[ ]*	[ ]*	[ ]*
[ ]*	[ ]*	[ ]*	[ ]* <sup>2</sup>
[ ]*	[ ]*	[ ]*	[ ]*
[ ]*	[ ]*	[ ]*	[ ]*
[ ]*	[ ]*	[ ]*	[ ]*

1. [ ]\*.
2. [ ]\*.

\* Confidential material redacted and separately filed with the Commission.

Table 6.2.2 Investigational New Drug Product Container/ Closure System

Container/Closure Component	Material	Manufacturer
[ ]*	[ ]*	[ ]*
[ ]*	[ ]*	[ ]*
[ ]*	[ ]*	[ ]*

**6.3 Manufacturer**

The RUT100-05 drug product is manufactured and packaged by for Ruthigen, Inc. by Oculus Innovative Sciences. The manufacturer contact information is provided below.

Oculus Innovative Sciences  
 1129 North McDowell Boulevard  
 Petaluma, CA 94954  
 Establishment Registration Number: 3004554409

**6.4 Manufacturing Process**

**6.4.1 Manufacturing Area Description**

The formulation and filling areas used for the production of the RUT100-05 drug product are classified and monitored as [ ]\*.

**6.4.2 Manufacturing Process Description**

A [ ]\* of [ ]\* is [ ]\* to the [ ]\*. [ ]\* of [ ]\* and [ ]\* are then [ ]\* to the [ ]\* and [ ]\* to [ ]\*. A [ ]\* of [ ]\* ([ ]\* as a [ ]\*) is then [ ]\* to the [ ]\* and [ ]\* to [ ]\*. With [ ]\*, [ ]\* is [ ]\* into the [ ]\* in the [ ]\* to [ ]\* the [ ]\*, [ ]\*. An [ ]\* of [ ]\* is [ ]\*, as [ ]\*, to the [ ]\* to [ ]\* the [ ]\*. If [ ]\* for [ ]\*, [ ]\*, [ ]\* ([ ]\* as a [ ]\*) [ ]\* be [ ]\* to the [ ]\*. The [ ]\* is [ ]\* into [ ]\* and capped. The bottled drug product is then sterilized by a [ ]\*.

\* Confidential material redacted and separately filed with the Commission.

## 6.5 Sterilization Process

Sterilization is performed by [ ]\* of [ ]\* into the [ ]\*, [ ]\* are [ ]\* at [ ]\*. The sterilizer facility contact information is provided below: [ ]\*.

[ ]\* are [ ]\* per [ ]\* and [ ]\* according to [ ]\* in a [ ]\* ([ ]\*). Sterilization is completed using the following process parameters:

- [ ]\*: [ ]\*
- [ ]\*: [ ]\*
- [ ]\*: [ ]\* per [ ]\*

[ ]\* are [ ]\* and [ ]\* to Oculus from [ ]\*. Finished product labels are applied to the bottles and shrink bands to the caps. The units are [ ]\* in [ ]\* during [ ]\*. The process is visualized in Figure 6.1.

Figure 6.1 RUT100-05 IND Manufacturing Process Flow Diagram

[ ]\*

\* Confidential material redacted and separately filed with the Commission.

## 6.6 Proposed IND Finished Product Specifications

The proposed IND tests, acceptance criteria and justification for the investigational drug, product RUT100-05 are listed in Table 6.6.1.

Table 6.6.1 Proposed IND Test and Specifications

<b>Test</b>	<b>Specification</b>	<b>Justification</b>
[ ]*	[ ]*	[ ]*
[ ]*	[ ]*	[ ]*
[ ]*	[ ]*	[ ]*
[ ]*	[ ]*	[ ]*
[ ]*	[ ]*	[ ]*
[ ]*	[ ]*	[ ]*
[ ]*	[ ]*	[ ]*
[ ]*	[ ]*	[ ]*
[ ]*	[ ]*	[ ]*
[ ]*	[ ]*	[ ]*
[ ]*	[ ]*	[ ]*

\* Confidential material redacted and separately filed with the Commission.

Table 6.6.1 Proposed IND Test and Specifications

[ ]*	[ ]*	[ ]*
[ ]*	[ ]*	[ ]*

**6.7 Analytical Methodology**

The proposed IND analytical test methodologies for the RUT100-05 drug product are listed in Table 6.7.1.

Table 6.7.1 Proposed IND Tests and Methodology

Test	Methodology
[ ]*	[ ]*
[ ]*	[ ]*
[ ]*	[ ]*
[ ]*	[ ]*
[ ]*	[ ]*
[ ]*	[ ]*
[ ]*	[ ]*
[ ]*	[ ]*
[ ]*	[ ]*
[ ]*	[ ]*
[ ]*	[ ]*
[ ]*	[ ]*
[ ]*	[ ]*
[ ]*	[ ]*
[ ]*	[ ]*

**6.8 Stability Finished Dosage Form**

Stability testing will be conducted on a [ ]\* of [ ]\* ([ ]\*) [ ]\* of [ ]\* to ensure the quality of the drug product throughout the expected period of the proposed clinical study program. The proposed stability study program for the IND is described in section 6.8.2.

**6.8.1 Stability of Representative Research and Development Lot**

[ ]\* of the manufacturing process and final [ ]\* ([ ]\*) proposed for [ ]\* and clinical batch materials has been [ ]\* and is [ ]\* on stability. The lot has been placed on stability at [ ]\* ([ ]\*) and [ ]\* ([ ]\*) storage conditions. The available stability data for the lot is presented in tables 6.8.1.1 and 6.8.1.2.

\* Confidential material redacted and separately filed with the Commission.

### Schedule 3

## DEVELOPMENT AND COMMERCIALIZATION PLAN

### **Overview**

We are a biopharmaceutical company focused on the discovery, development, and commercialization of pharmaceutical-grade hypochlorous acid, or HOCl, based therapeutics designed to prevent and treat infection in invasive applications. Our lead drug candidate, RUT58-60, is a broad spectrum anti-infective that we are developing for the prevention and treatment of infection in surgical and trauma procedures. We are focusing RUT58-60 for use initially in abdominal surgery due to the large addressable market, high rate of post-surgical infection associated with abdominal surgery, the high-impact opportunity that abdominal surgery offers us in the clinical trial setting to expose multiple internal organs to RUT58-60 at one time, and feedback from surgeons identifying post-surgical infection in abdominal surgery (relative to other surgeries) as a significant unmet medical need.

Our goal is to become the first company to market RUT58-60 as a drug containing hypochlorous acid for the prevention and treatment of infection in invasive surgeries in the United States. We believe that RUT58-60 has the potential to significantly reduce the rate of post-surgical infections, reduce the use of systemic antibiotics that have proven to be ineffective against certain common resistant strains of bacteria, including methicillin-resistant staphylococcus aureus, or MRSA, and vancomycin-resistant enterococcus, or VRE, reduce the negative side effects associated with the increasingly widespread use of antibiotics, accelerate post-surgical healing which should lead to quicker patient discharge from the hospital, and ultimately reduce hospital readmission rates. We plan to initiate our Phase 1/2 clinical trial for RUT58-60 in the United States in the fourth quarter of 2013 and pending the successful completion of that trial and our planned pivotal clinical trials, we plan to submit our new drug application, or NDA, to the U.S. Food and Drug Administration, or FDA, in early 2017.

We believe that RUT58-60 will complement the paid for performance paradigm and it is designed to reduce the overall healthcare costs associated with post-surgical infections and improve hospital economics. We believe the benefits of RUT58-60 will be significant:

- the drug mimics the human body's own infection-fighting mechanism,
- there is no evidence of toxicity or other negative side effects in our animal and other preclinical studies,
- our preclinical studies have not produced resistant bacteria, and
- the drug appears to provide broad spectrum anti-microbial effect with significant pro-healing attributes.

We believe that RUT58-60 has the potential to be used as a prophylactic therapy to prevent and treat infections, and may accelerate patient discharge from the hospital and ultimately lead to an overall reduction in hospital readmission rates.

The benefits of hypochlorous acid in preventing infection have been well-demonstrated in products with lower concentrations of hypochlorous acid than RUT58-60. To date, hypochlorous acid based products have only been cleared for use as medical devices for topical applications in the United States, Europe and certain other countries. Earlier formulations have not been able to achieve therapeutic indication status, primarily due to their lack of stability and therefore have been limited for use as topical applications. Historically, the lack of stability has posed a vexing problem to companies hoping to pursue hypochlorous acid products for therapeutic indications in invasive applications and has prevented these companies from being able to conduct the clinical trials necessary to prove whether HOCl is safe and effective for use as a therapeutic.



Hypochlorous acid based products have been used successfully to prevent infection in topical applications and have been sold commercially since at least 2005 by other companies, generally as medical devices or for the disinfection of medical devices. Several of these hypochlorous acid based products have been commercialized as medical devices by Oculus Innovative Sciences, Inc., or Oculus, our parent company and the licensor of our technology. Through our license and supply agreement with Oculus that will take effect upon the completion of this offering, we have obtained exclusive rights to the RUT58-60 technology, as well as a proprietary method of manufacturing and producing hypochlorous acid with pharmaceutical potential by incorporating additional small molecules, such as magnesium, without sodium hypochlorite, the result of which increases the stability and biocompatibility of the compound. We believe our recent enhancements to the stability and biocompatibility of the compound will allow us to expand the use of hypochlorous acid so that it may be used in direct contact with internal organs and thus, for invasive applications, including surgical and trauma procedures, as well as additional clinical indications. With these enhancements, we believe our lead product candidate will be able to meet the safety and efficacy standards that the FDA requires for the approval of a new drug. Subject to FDA approval of RUT58-60 as a drug, we plan to commercialize our product for invasive applications.

There are approximately 30 million surgical and trauma procedures in the United States per year, approximately 7 million of which are abdominal surgeries. Our initial goal is to obtain FDA approval for RUT58-60 for the prevention of infection associated with abdominal surgery and thereafter we plan to pursue FDA approval for RUT 58-60 for use in other types of surgical procedures as well as additional clinical indications. We expect to commence our Phase 1/2 clinical trial in the fourth quarter of 2013. Pending the successful completion of that trial, we plan to conduct the pivotal clinical trials necessary to obtain regulatory approval in the United States. Our goal is to obtain regulatory approval from the FDA and begin marketing RUT58-60 for the prevention of infection associated with abdominal surgery as early as 2017.

If we are successful in receiving FDA approval for RUT58-60 for the prevention of infection in abdominal surgery, we plan to pursue other types of surgeries, including cardiac, pulmonary and spinal, among others. We believe that the safety and tolerability profile of RUT58-60, combined with its broad-range antimicrobial potency without specificity, offer a practical and unique approach to stem the high rate of hospital acquired infections and infections resulting from complications in surgeries and the increasing emergence of new antibiotic resistant bacteria that pose a significant risk to public health. We believe that RUT58-60 represents a significant innovation over existing uses of hypochlorous acid in topical applications and over systemic antibiotics, which are the current standard of care for the prevention and treatment of infection in surgical and other invasive applications, and has the potential to raise the clinical bar for anti-infective products generally in the face of increasing headwinds.

In addition to the United States, we plan to seek regulatory approval to commercialize RUT58-60 in Canada, Europe and Japan. Under our license and supply agreement with Oculus that will take effect upon the completion of this offering, we have exclusively licensed the hypochlorous acid technology relating to RUT58-60 for commercialization in the United States, Europe, Japan and Canada. Together, these markets represented approximately 71% of the global medicines market in 2011. In parallel with our clinical development activities for RUT58-60, we have commenced discussions with various pharmaceutical companies for potential partnership and collaboration activities for RUT58-60 in the United States, Canada, Europe and Japan.

### **Our Strategy**

Our goal is to be the first company to market hypochlorous acid based drugs for the prevention and treatment of infection in invasive procedures. By doing so, we hope to be able to reduce the number of post-surgical infections, reduce the increasingly widespread use of systemic antibiotics and the negative side effects associated with them, accelerate post-surgical healing which should lead to quicker patient discharge from the hospital, and reduce hospital readmission rates. The key elements of our strategy to achieve this goal are listed below.

- Initiate and complete clinical trials for our lead drug candidate, RUT58-60, for the first indication (abdominal surgery) and obtain regulatory approval to market as a drug in the United States.
- Establish our own manufacturing facility in compliance with the FDA's cGMP requirements for manufacturing drugs.
- Commercialize RUT58-60 in the United States either through a direct sales force or with a partner.
- Engage strategic partners to develop, obtain regulatory approval for, and commercialize RUT58-60 for invasive use in Europe and Japan.
- Expand the use of, and obtain regulatory approval for, RUT58-60 for use in other types of surgeries and traumatic procedures.
- Leverage our proprietary hypochlorous acid chemistry technology to develop a pipeline of innovative drugs for the prevention and treatment of infection in surgical and other invasive applications.

### **Our Solution**

We believe that hypochlorous acid, the active pharmaceutical ingredient in RUT58-60 and other drug candidates that we plan to develop in the future, has several potential benefits over systemic antibiotics, which are the current standard of care for the prevention of infection associated with surgical and trauma procedures, as described below.

- *Broad Spectrum Activity.* RUT58-60 has been shown in non-clinical studies to kill bacteria, viruses, spores, and fungi through common mechanisms of action, including by denaturation, a process in which the structure of surface proteins on the microorganism is irreversibly changed or damaged, which results in the destruction of pathogen.
- *Effective Against Existing Antibiotic Resistant Strains of Bacteria.* RUT58-60 has been shown in non-clinical studies to eradicate MRSA, VRE, and other antibiotic resistant microorganisms. RUT58-60's biologic activity is localized and fast-acting, which results in rapid bacterial destruction; in vitro studies have demonstrated potent 30-second kill times against several commonly found, clinically relevant, aggressive treatment-resistant bacteria.
- *Multi-targeted; Does Not Promote Emergence of Superbugs.* We believe that RUT58-60 has the potential to be used broadly as a prophylactic agent to prevent infections in surgical patients because it does not promote resistance to bacteria and therefore does not increase the emergence of drug-resistant pathogens. RUT58-60 does not target specific strains or receptor targets that the microorganism can then quickly mutate to induce resistance. Further, exposure to hypochlorous acid causes irreversible destabilization of protein structures necessary for continued metabolism for bacteria and other microbes.
- *Pro-healing Potential.* Hypochlorous acid products have demonstrated faster tissue healing in a number of published studies. Although the mechanism of action for incision site healing has not been formally established in RUT58-60, we believe, based on initial clinical trials conducted by physicians in Mexico, that incision sites will heal quicker, resulting in faster patient recovery and discharge from the hospital.
- *Mimics Body's Natural Microbe-Fighting Mechanism.* Human bodies have evolved over hundreds of years to produce hypochlorous acid naturally to kill infection-causing microbes quickly and without creating the opportunity for microbes to mutate and become resistant. We believe that we have chemically engineered RUT58-60 to mimic the body's natural response to unfamiliar and unwanted organisms, without the undesirable side effects resulting from the proliferation and overuse of antibiotics.

- *No Change to Surgeon Behavior Required.* Sterile saline is currently the most commonly used irrigation solution to prevent infection during and following surgery when lavage is used to wash the surgical site following surgical and trauma procedures, but it does not contain the antiseptic benefits traditionally associated with antibiotics to prevent post-surgical infection. The use of a lavage wash in surgeries is not new and therefore, we believe that the replacement of saline (or other currently used post-operative irrigation solutions) with RUT58-60 in surgical settings will be an easy and logical transition for surgeons and will not require additional training, time, education, ramp up or behavior changes by surgeons.
- *Prepackaged, Sterilized, Ready to Use.* We believe that RUT58-60, if approved by the FDA, will be the only prepackaged, sterilized, ready-to-use hypochlorous acid based drug designed to prevent infection following surgery. We intend to package RUT58-60 in convenient, sterile packaging that will not require mixing or solution preparation prior to use, thereby reducing the need for human intervention and further minimizing opportunities to introduce other organisms that may cause infection and the risk of medical error.
- *Stable Formulation.* RUT58-60 is not expected to require special handling precautions or storage requirements beyond those typically required for similar sterile products found in hospital and other indoor settings. Laboratory tests suggest that RUT58-60 may have a shelf life ranging from one to two years depending on the size and type of packaging. We believe that RUT58-60 is a unique, shelf stable form of hypochlorous acid that has the potential to meet the FDA's requirements for a drug.
- *Enhanced Biocompatibility for Internal Use.* We believe RUT58-60 is the first and only form of hypochlorous acid based drug designed for internal use. We believe RUT58-60 represents an innovative way to improve the potential pharmaceutical properties of hypochlorous acid by incorporating additional small molecules, such as magnesium, without sodium hypochlorite, the result of which enhances the biocompatibility of the compound in a manner that allows for direct exposure to internal organs.
- *Hospital Cost Savings Potential.* We believe that RUT58-60 has the potential to improve surgical outcomes and lower hospital costs by preventing infection, decreasing the time to patient discharge and reducing hospital readmission rates. Post-surgical infections are costly and, under new government regulations and payor policies, these infections are increasingly not covered for reimbursement. High patient costs associated with the treatment of infections may be related to longer hospitalizations and extended care, patient isolation due to the high rates of infection transmission, and the use of expensive systemic antibiotics used to target infection. Post-surgical infection may also undermine the healing process, prolong healing time and increase hospital readmissions after initial discharge. Eventually, we believe that RUT58-60 may also help reduce the use of systemic antibiotics, thereby lowering overall cost of the hospital visit.