

foiapa

18-04077-E

**From:** Mark Edwards <medwards@biosciadvisors.com>  
**Sent:** Saturday, April 21, 2018 3:28 AM  
**To:** foiapa  
**Subject:** FOIA Request

**RECEIVED**

APR 23 2018

Office of  
FOIA Services

I would like to request access to Exhibit 10.63 to the 3/31/08 10-Q, filed by Anesiva, Inc. on 5/8/2008. Confidential treatment was sought as to certain portions when initially filed with the Commission.

In the event that confidential treatment has not expired or has been extended, I further request that you send me the expiration date(s) from the relevant CT order(s) so I will know when I should resubmit my request.

I authorize up to \$61 in search and retrieval fees. Please send the exhibit(s) by PDF if possible.

Sincerely,

Mark

Mark G Edwards  
Managing Director  
Bioscience Advisors  
2855 Mitchell Dr., Suite 103  
Walnut Creek, CA 94598  
[medwards@biosciadvisors.com](mailto:medwards@biosciadvisors.com)  
925 954-1397



UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
STATION PLACE  
100 F STREET, NE  
WASHINGTON, DC 20549-2465

Office of FOIA Services

May 17, 2018

Mr. Mark G. Edwards  
Bioscience Advisors  
2855 Mitchell Dr., Suite 103  
Walnut Creek, CA 94598

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552  
Request No. 18-04077-E

Dear Mr. Edwards:

This letter is in response to your request, dated April 21, 2018 and received in this office on April 23, 2018, for Exhibit 10.63 to the March 31, 2008, 10-Q, filed by Anesiva, Inc., on May 8, 2008.

The search for responsive records has resulted in the retrieval of 21 pages of records that may be responsive to your request. They are being provided to you with this letter.

If you have any questions, please contact me at [fultonc@sec.gov](mailto:fultonc@sec.gov) or 202-551-8186. You may also contact me at [foiapa@sec.gov](mailto:foiapa@sec.gov) or (202) 551-7900. You also have the right to seek assistance from Lizzette Katilius as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or [Archives.gov](http://Archives.gov) or via e-mail at [ogis@nara.gov](mailto:ogis@nara.gov).

Sincerely,

A handwritten signature in cursive script, reading "Charlotte Fulton".

Charlotte Fulton  
FOIA Research Specialist

Enclosure

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EXHIBIT 10.63

## LICENSE AND DISTRIBUTION AGREEMENT

**THIS LICENSE AND DISTRIBUTION AGREEMENT** is made and entered into as of 16<sup>th</sup> day of April, 2008, by and between Anesiva, Inc., a Delaware corporation, having a principal place of business at 650 Gateway Boulevard, South San Francisco, California 94080 (hereinafter referred to collectively as, "ANESIVA") and GREEN VISION COMPANY with its principal place of business at Al Azizya, Doha, Qatar (hereinafter referred to as "GVC"), which hereby agree as follows:

### RECITALS

**WHEREAS** ANESIVA owns the patent rights, Methods and Technical Know-How relating to the manufacture and use of their proprietary Product, and

**WHEREAS** ANESIVA owns certain trade names, trademarks, logos, emblems and indicia of origin which are used in association with the Product, and

**WHEREAS** GVC is desirous of obtaining from ANESIVA the exclusive right and license to market and sell the Product as well as the methods and Technical Know-How (as such term is hereinafter defined) in the Territory (as such term is hereinafter defined) under the Proprietary Marks (as such term is hereinafter defined), upon the terms and subject to the conditions hereinafter set forth; and

**NOW, THEREFORE**, this Agreement witnesses that in consideration of the mutual covenants and agreements herein contained and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto hereby covenant and agree with each other as follows:

#### 1. Definitions

Where used in this Agreement the following terms shall have the following meanings:

1.1. **"Affiliate"** means, with respect to any Person, any other Person who directly or indirectly controls, is controlled by, or is under direct or indirect common control with, such Person, and includes any Person in like relation to an Affiliate. A Person is deemed to control another Person if such Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such other Person, whether through the ownership of voting securities, by contract or otherwise; and the term "controlled" has a corresponding meaning.

1.2. **"Agreement"** means this Agreement as is or it may be amended or supplemented from time to time, and the expressions "hereof", "herein", "hereto", "hereunder", "hereby" and

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similar expressions refer to this Agreement and not to any particular section (hereinafter “§”) or other portion of this Agreement.

1.3. **“Business Day”** shall mean a day other than Saturday, Sunday or any day on which banks located in the Territory, are authorized or obligated to close. Whenever this Agreement refers to a number of days, such number shall refer to calendar days unless Business Days (or business days) are specified.

1.4. **“Commercially Reasonable”** shall mean a Party’s reasonable efforts and diligence in manufacturing and commercializing the Product in accordance with its business, legal, medical and scientific judgment, such reasonable efforts and diligence to be in accordance with the efforts and resources the Party would use for a product owned by it or to which it has rights, which is of similar market potential at a similar stage in its product life, taking into account the competitiveness of the marketplace, the ability of a contract manufacturer to deliver product, the proprietary position of the compound, the regulatory structure involved, the profitability of the applicable Product, and other relevant factors including, without limitation, technical, legal, scientific or medical factors.

1.5. **“Customer”** shall mean any [hospital, any pharmacy, any wholesaler or sub distributor that place demand order] for the Product, in the Territory.

1.6. **“Documents”** means, collectively, all books, pamphlets, bulletins, memoranda, letters, notices or other publications or documents prepared by or on behalf of ANESIVA for use by GVC, setting forth information, formulae, production specifications, advice, standards, requirements, operating procedures, instructions or policies relating to the Product.

1.7. **“Effective Date”** shall mean the date of last signature of the Parties hereto.

1.8. **“GMP”** shall mean current Good Manufacturing Practices promulgated by U.S. Food and Drug Administration.

1.9. **“Government Regulatory Authority”** shall mean any court, tribunal, arbitrator, authority, agency, commission, official or other instrumentality of the United States of America, Ministry of Health / National Health Authority in the countries of the Territory (Territory Health authority) and/or other political subdivision in the Territory or other governmental instrumentality of a United Nations recognized sovereign state having subject matter jurisdiction over the Product(s) as the case may be.

1.10. **“Generally Accepted Accounting Principles”** shall mean accounting rules used to prepare, present, and report financial statements for a wide variety of entities, including publicly-traded and privately-held companies, non-profit organizations, and governments. Generally GAAP includes local applicable Accounting Framework, related accounting law, rules and Accounting Standard.

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1.11. **“Ministry of Health / National Health Authority”** shall mean the department of the government of each country in the territory with responsibility for national public health, and any successor agency thereto.

1.12. **“Improvements”** means any future innovations, inventions, designs, plans, drawings, specifications, techniques, data and technical information relevant to the use (indications) or sale of the Product including, but not limited to, modified packaging.

1.13. **“Law” or “Laws”**, as the case may be, shall mean all laws, statutes, rules, regulations, ordinances, guidelines and other pronouncements having the effect of law in any country with jurisdiction over either of the Parties and/or Product(s) or any domestic or foreign state, province, county, city or other political subdivision or of any Health Registration Authority or Regulatory Authority in the Territory.

1.14. **“Exchange Rate”** shall mean the spot Exchange Rate published in *The Wall Street Journal* as quoted by Reuters at 4:00 PM on the prior business day.

1.15. **“Manufacturing Cost”** shall mean, with respect to Product, the sum of the following, all of which shall be calculated in accordance with U.S. Generally Accepted Accounting Principles:

(a) The amounts paid by ANESIVA to any third party for (i) providing raw materials and packaging materials for producing the Product, (ii) manufacturing, filling and/or finishing Product or any component thereof, (iii) storing, insuring and packaging Product, and (iv) release and stability testing Product, including with respect to the foregoing, all taxes (other than income taxes) and customs duty charges imposed by governmental authorities with respect thereto, to the extent paid by ANESIVA and not reimbursed or refunded by a third party;

(b) The direct costs and charges incurred by ANESIVA in connection with the manufacture, filling, finishing, testing (including direct quality control and quality assurance activities), storing, insuring and packaging Product not otherwise accounted for pursuant to subsection (a) above;

(c) A reasonable allocation of indirect labor, administration costs and facilities costs (including electricity, water, sewer, waste disposal, property taxes and depreciation over the expected life of buildings and equipment) attributable to the manufacture, filling, finishing, testing, storing, insuring and packaging of Product; provided that such indirect labor, administration costs and facilities costs shall only include an allocation, to the units or sections directly engaged in the activities listed in the subsection (b) above, of such indirect labor, administration costs and/or facilities costs incurred by ANESIVA.

Without limiting the generality of the foregoing provisions of this §1.14, Manufacturing Cost shall exclude, all costs and charges related to or occasioned by unused manufacturing capacity; the manufacture of other products at ANESIVA's or a third party contractor's facility; depreciation of property, plant or equipment not specifically related to manufacturing Product; allocation of administrative costs and general corporate overhead of ANESIVA or its third party

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contractors; ANESIVA's cost of capital, whether or not such capital is attributable to the manufacturing of any Product; and any employee costs associated with equity incentive plans.

1.16. **"Marketing Authorization"** shall mean the final approval of registrations and permits required by applicable Government Regulatory Authority in the Territory, for the importation into and for the marketing, sale and distribution of the Product in such Territory.

1.17. **"Methods and Technical Know-How"** means all information, knowledge and experience of a technical and commercial nature, including trade secrets, the Specifications, the Documents, information and data relating to techniques for, methods of or practices in the use and sale of the Product.

1.18. **"Net Sales"** shall mean, in accordance with the Generally Accepted Accounting Principles published by the Financial Accounting Standards Board of the United States, the amount invoiced by GVC sales of the Product in the Territory to a Third Party, less:

(a) discounts (including without limitation cash discounts and quantity discounts), charge-back payments, and customer rebates;

(b) credits or allowances actually granted upon claims, damaged goods, rejections, or returns of Product other than any such credits or allowances arising from manufacturing defects or any defect attributable to ANESIVA, including but not limited to credits, allowances and related costs attributable to Product recalls.

1.19. **"Party"** means a Party to this Agreement and any reference to a Party includes its successors and permitted assigns; **"Parties"** means every Party.

1.20. **"Person"** shall mean any legal person including, for example, an individual, corporation, partnership, Limited Liability Company, trust, business trust, association, Joint Stock Company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, governmental authority or any other form of entity.

1.21. **"Pre-registration Sales"** means sales generated prior to the registration of Zingo in territory. In this case GVC will raise a purchase order to ANESIVA specifying the quantity and the name of the account to be supplied. Upon receiving the purchase order from GVC, ANESIVA will supply the account mentioned in the purchase order with the requested quantity. ANESIVA will issue the invoice for the supplied quantity to GVC and will issue a letter to the account along with the shipment requesting the account to pay directly to GVC for the quantity shipped. GVC will invoice the account directly for the quantity supplied by ANESIVA. GVC shall further remit the payment to ANESIVA.

1.22. **"Product"** means ANESIVA's (lidocaine hydrochloride monohydrate) powder intradermal injection system, 0.5mg, indicated for use on intact skin to provide topical local analgesia prior to venipuncture or peripheral intravenous cannulation and marketed in the United States under the brand name Zingo™.

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1.23. **“Proprietary Marks”** means the marks, trademarks, trade names and other commercial symbols and related logos relating to the Product for use in the Territory, together with such other trade names, trademarks, symbols, logos, distinctive names, service marks, marks, logo designs, insignia or otherwise which may be designated by ANESIVA. Proprietary Marks may be updated from time to time.

1.24. **“Quality Assurance Department” or “QA”** shall mean the group or department that performs the quality review functions. QA reviews and approves quality-related documents and procedures.

1.25. **“Recall”** shall have the meaning set forth in §9.3.

1.26. **“Specifications”** means all specifications, methods, applications, criteria, qualities, requirements and all other information in connection with the use, handling, distribution, marketing and/or sale of the Product published, promulgated or conveyed by or on behalf of ANESIVA to GVC in any manner whatsoever, including any manual, specification booklet, letter, notice, memorandum or other written from, from time to time.

1.27. **“Serious Adverse Events”** shall mean any adverse experience that result in any of the following outcomes: death, a life-threatening experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening or require hospitalization may be considered a serious adverse event when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

1.28. **“Term”** shall have the meaning set forth in §11

1.29. **“Territory”** shall mean [UAE, Kuwait, Qatar, Bahrain, Oman, Saudi, Jordan and Lebanon].

1.30. **“[Training Devices]”** shall mean a [Zingo like device] used for [demonstration] of a [functioning] device. [Training Device] is not intended to work as a [sample] and does not provide any [therapeutic value].

## **2. Terms, Grant of Licences, Regulatory Submissions and Drug Release Testing, and Governance**

2.1. The sole and exclusive license granted in §2 shall have a Term composed of the [Initial Term] and [any Renewal Term] or [Renewal Terms].

2.2. The Initial Term shall begin as of the Effective Date of this Agreement between the Parties and shall continue in effect until [ten (10) years] from the date of execution of this Agreement.

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2.3. [Renewal] Terms shall be the [automatic extension] of this Agreement for [additional periods] of [three (3) years] unless [one Party notifies] the [other Party] that it does not intend to [renew the Agreement] no less than [one (1) year prior] to the [expiration] of the [Initial Term] or [any Renewal Term].

2.4. Subject to the provisions of this Agreement, and solely during the Term, ANESIVA hereby:

(a) covenants and agrees to license exclusive right to the Product [and Improvements] to GVC in the Territory to enable GVC to promote, market and sell the Product in the Territory;

(b) grants to GVC the exclusive right and license to use the Proprietary Marks in connection with the marketing, distribution and sale of the Product within the Territory and

(c) grants GVC a royalty-bearing license to all intellectual property related to the Product including, but not limited to, the Proprietary Marks for GVC's use in the Territory as may be necessary and required under the Laws and regulations and a fully paid license to all governmental authorizations, product documentation, marketing materials and the like. All costs associated with registering or maintaining the Proprietary Marks or other intellectual property will be [at the sole cost of ANESIVA].

2.5. GVC shall be responsible for the application, prosecution and maintenance of Marketing Authorizations in the Territory for the Product, with the Market Authorization remaining in GVC's name during the term of the Agreement, under the following conditions:

(a) GVC agrees to [pay] the Marketing Authorization application and maintenance [fees] which are [directly payable] to Territory Health Authority, including [fees] related to any required amendments to the initial application;

(b) ANESIVA agrees to provide GVC with a current and complete copy of the U.S. approved regulatory dossier for the Product and to supplement this regulatory dossier as new data becomes available. GVC agrees to modify this dossier in accordance with the requirements of the Territory for submission in the Territory.

(c) ANESIVA agrees to support GVC in addressing any Territory Health Authority questions subsequent to submission and approval.

(d) Marketing authorizations for the Product shall remain in GVC's name and under its control during the term of the license. GVC and ANESIVA will [share the cost] of any Territory Health Authority manufacturing site inspection that requires [longer than two (2) days] on site at ANESIVA or ANESIVA contract manufacturer. In the case where Territory Health Authority requires a [manufacturing change] that is not required by either U.S. or EU regulatory authorities, then this [change] will be [paid for] by [GVC].

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(e) GVC agrees to conduct and [pay for] drug release testing before the shipment of Product for human use in the Territory, which is required pursuant by Territory Law for Product imported into the Territory. With the lab conducting such testing to be mutually agreed upon.

2.6. Both Parties shall appoint a project leader within [thirty (30) days] of signing the Agreement, through which all communications regarding this Agreement will be initially directed. The project leaders will facilitate direct communication between functional experts as needed to manage activities under the Agreement.

2.7. The Parties shall make all reasonable efforts to amicably resolve any disputes which may arise out of or relating to the application of this Agreement through discussions between senior executives of the Parties. In the event that the Parties fail to resolve any dispute, the Parties will seek resolution through a non-binding mediation using a mutually acceptable industry expert. Only if all good faith attempts have failed, then the dispute shall be finally settled by arbitration under the rules of the International Chamber of Commerce by one (1) arbitrator appointed in accordance with the said Rules. The proceedings shall take place in [California] and shall be conducted in [English]. This provision shall not preclude the right of either Party to address any competent Court or Tribunal in respect of obtaining interim measures.

### **3. Proprietary Rights**

3.1. ANESIVA shall register the Proprietary Marks and such other intellectual property rights as required for the Territory within a Commercially Reasonable time after its execution of this Agreement if such Proprietary Marks and other intellectual property rights have not already been registered. All registrations shall be at [ANESIVA's expense].

3.2. GVC confirms that all right, title and interest in the Proprietary Marks or related to the Proprietary Marks is the sole property of ANESIVA and this Agreement shall not operate to convey any interest in the Proprietary Marks to GVC.

3.3. ANESIVA shall include the applicable Proprietary Marks on all packages of the Product delivered to GVC (or as directed by GVC to its customs brokers). GVC shall make use of the Proprietary Marks in all materials and activities related to the marketing, sale and distribution of the Product. The Proprietary Marks used by GVC shall comply with the form of the Proprietary Marks as registered in the Territory.

3.4. At all times, GVC shall use the ANESIVA registered trademarks in reference to the applicable Product in the Territory unless prohibited by Law of the Territory. In any such event, ANESIVA and GVC shall meet to resolve any such legal prohibition in accordance with the Laws and regulations of the Territory.

### **4. Payment and Prices**

4.1. GVC shall pay ANESIVA a [non-refundable upfront-payment] of [fifty thousand (US\$50,000) United States Dollars] as follows: [

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- a. US\$25,000 within thirty days upon signing of the agreement.
- b. US\$25,000 within thirty days upon delivery of the first order to the territory (prior to registration).]

4.2. GVC shall pay ANESIVA a [non-refundable] milestone payment of [one hundred thousand (US\$100,000) United States Dollars] upon [registration] of the Product in the Territory. This payment of [US\$100,000] will be [divided equally] to the [eight countries] of the territory [(UAE, Kuwait, Qatar, Bahrain, Oman, Saudi, Jordan and Lebanon)] and to be paid within [30 days] from issuing the [registration certificate].

4.3. GVC shall purchase the Product from ANESIVA at ANESIVA's Manufacturing Cost. Such payments shall be made [sixty (60) days] after the Product is received by GVC, subject to inspection by GVC.

4.4. Sales Milestone Payments:

GVC will also pay ANESIVA certain sales milestones that will become due [once and only if] the Net Sales of Licensed Product in the Territory [exceed] the following [thresholds] during a Marketing Year:

\$250,000 when the annual sales exceed \$7 million  
\$500,000 when annual sales exceed \$10 million  
\$1,000,000 when the annual sales exceed \$15 million  
\$2,000,000 when the annual sales exceed \$25 million]

4.5. Royalty on Net Sales: GVC shall pay a [flat] royalty of [twenty (20%)] of Net Sales to ANESIVA.

4.6. Within [fifteen (15) days] after the [end] of any [calendar quarter] GVC shall deliver to ANESIVA a true and accurate report of Net Sales during such [calendar quarter]. Any payments due under this Agreement shall be made in U.S. Dollars, calculated based on Exchange Rate and paid by wire transfer to a bank and account designated in writing by ANESIVA. For payments, ANESIVA will submit written invoices on the day Product is shipped to GVC. Payment of each such invoice not subject to a good faith dispute will be due in full within [twenty-one (21) days] following receipt of invoice. Invoices shall be sent to the following address:

GREEN VISION COMPANY  
Al Azizya  
Doha - Qatar  
P.O Box 55272  
Telephone: +974 4517815  
Fax: +974 4517247

5. Product Supply, Shipping, Ordering

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5.1. Product sold to GVC for use in the Territory shall be [in finished packages ready] for commercial sale and are FCA (INCOTERMS 2000) ANESIVA's manufacturing plant (or any plant of a designated contract manufacturer) or at such other place as the Parties may mutually agree from time to time.

5.2. In consideration of the rights granted to GVC by ANESIVA pursuant to the provisions of §2, GVC will exclusively purchase its needs for the Territory of the Product subject to this license from ANESIVA (or from a contract manufacturer designated by ANESIVA) during [the Initial Term] or [any Renewal Term] or [Terms] of the Agreement.

5.3. In this regard, GVC agrees to:

(a) provide ANESIVA a [twelve (12) month non-binding] rolling forecast in unit terms [forty five (45) days prior] to each [quarter]. The first [quarter] of the [twelve (12) month] forecast shall be [binding]. ANESIVA will acknowledge acceptance of the forecast within [fifteen (15) days]. GVC will place a Purchase order for each [month fifteen (15) days prior] to the [start] of the [month]. ANESIVA will acknowledge the PO within [ten (10) days].

(b) [Six (6) months] prior to anticipated launch, GVC will provide ANESIVA with the first [twelve (12) month non-binding] rolling forecast in unit terms from launch date and a [three (3) year non-binding] forecast. [Annually] on [November 15], GVC will provide ANESIVA a [non-binding] forecast for the next [three (3) years].

(c) provide ANESIVA with not less than [sixty (60) days] lead time on: (i) all Product orders; (ii) all packing/labeling specifications for shipping; and (iii) all orders for literature and marketing materials, if any; and

5.4. Minimum purchase order volume for the Territory will be [twenty-five thousand (25,000)] units. ANESIVA shall package and deliver Product ordered by GVC no later than [sixty five (65) days] after receipt of such order. For the product supply to the [hospitals] prior to the registration from the Territory Health Authority, GVC shall be entitled to the purchase orders less than [twenty-five thousand (25,000)] units. Minimum purchase order volume applies only after registration in the Territory.

5.5. GVC shall place purchase orders for the Product demand prior to the registration in the Territory. GVC will raise a purchase order to ANESIVA specifying the quantity and the name of the account to be supplied. Upon receiving the purchase order from GVC, ANESIVA will supply the account mentioned in the purchase order with the requested quantity and will issue a letter to the account requesting the account to pay GVC directly for the quantity supplied. GVC will invoice the account directly and further remit the proceeds to ANESIVA.

5.6. The Product supplied to GVC shall be exactly same as the Product marketed in United States of America, with the exception of a customized label for the Territory (in English and Arabic). There shall be no other changes in the Product or packaging features or QA/QC testing requirements for the Territory.

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5.7. The Product supplied to GVC or its designee shall have a shelf life of at least [24 (twenty-four) months] with at least [seventy-five per cent (75%)] shelf life remaining at delivery. ANESIVA shall not be required to replace Product held in inventory by GVC whose shelf life has expired.

5.8. Product orders shall be packed and labelled by ANESIVA for international shipping, as specified by GVC, and picked up by the customs broker or shipping agent specified by GVC at ANESIVA's manufacturing facility or at any other mutually agreeable location pursuant to §5.1 above.

(a) GVC shall comply with the Specifications and ensure that packaging, labeling and delivery of the Product is in accordance with the applicable standards and Laws in the Territory; and

(b) GVC shall prepare, at its own expense, labels and package inserts for the Product in compliance with GMPs and the Marketing Authorization. GVC shall provide copy artwork in a format specified by ANESIVA for all printed components including product label, pouch, insert, carton, and shipper label content. GVC shall send such copy artwork to ANESIVA to obtain ANESIVA's suggested changes and final written approval. ANESIVA shall then source such labels and packages from approved vendors at ANESIVA's expense.

5.9. ANESIVA shall refrain from directly or indirectly selling the Product in the Territory to any Third Party during the Term

5.10. All expenses incurred by GVC in the handling, distribution, marketing and sale of the Product and in carrying out its obligations under this Agreement shall be paid by or on behalf of GVC.

## **6. Quality Agreement**

6.1. GVC and ANESIVA shall comply with the terms and conditions of the Quality Assurance Agreement, which will be agreed by the Parties and signed within [ninety (90) days] after the signing of this Agreement.

6.2. During the term of this Agreement and any renewal thereof, ANESIVA agrees to, in accordance with the Quality Agreement,:

- a. assist GVC in the handling, sales and service of the Product by transmitting to GVC such Specifications and other information reasonably required by it for such handling, sales and service as is available to ANESIVA, including copies of the Documents, and to advise GVC in writing, in advance of any change to the Specifications or shipping, storage or handling procedures for the Product; and

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b. furnish to GVC such continuing technical assistance and guidance as is from time to time reasonably required by GREEN VISION; however, in no event shall ANESIVA's response to such request for technical assistance shall be no later than [fifteen (15) business days] after receipt of such request; and

c. upon and subject to the terms and conditions of this Agreement, to manufacture, or to cause a third Party to manufacture, and to supply GVC with a sufficient supply of the Product to meet the needs of the Territory. Such Product shall be manufactured and packaged in accordance with GMP and shall conform to the specifications for the product as contained in the Marketing Authorization applications; and

d. to retain a reasonable and customary number of sample Product for quality assurance and control purposes (GVC agrees that any samples provided for QA/QC purposes shall not enter the commercial stream); and

6.3. ANESIVA acknowledges and agrees that the implementation of this Agreement requires the co-operation of both Parties and that the ability of each Party to carry out its obligations hereunder shall be dependent upon the other Party performing its obligations (including its responsibilities pursuant to the Quality Assurance Agreement and the Pharmacovigilance Agreement).

## **7. Representations and Warrants of ANESIVA**

ANESIVA hereby represents and warrants to and in favour of GVC as follows:

7.1. ANESIVA is a corporation duly incorporated validly subsisting under the Law of the State of Delaware and has the corporate power to enter into this Agreement and to perform its obligations hereunder.

7.2. This Agreement has each been duly authorized, executed and delivered by ANESIVA and is a legal, valid and binding obligation of ANESIVA.

7.3. ANESIVA has the right to enter into this Agreement and to grant to PL the licensing arrangements outlined herein.

7.4. As of the Effective Date:

(a) to the best of ANESIVA knowledge, the use or practice of the Methods and Technical Know-How does not infringe any patent right owned by any third Party in the Territory;

(b) ANESIVA is the sole record and beneficial owner or exclusive licensee of the Methods and Technical Know-How;

(c) ANESIVA has not granted any other licences or rights of any kind in the Product or the Methods and Technical Know-How to any third Party in the Territory;

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7.5. ANESIVA expressly warrants and represents that the Product supplied to GVC shall conform to the Specifications therefore and be free from defects; be manufactured in accordance with GMP and such other applicable Laws and regulations in the Territory and in accordance with the approved Product specifications therefore in the Territory and in accordance with the Quality Agreement; and be fit for the intended use.

7.6. The execution and delivery of this Agreement do not conflict with or violate any requirement of applicable Laws or regulations.

## **8. Representations and Warrants of GREEN VISION**

GVC hereby represents and warrants to and in favour of ANESIVA as follows:

8.1. GVC is a corporation duly incorporated validly subsisting under the Law of Qatar and has the corporate power to enter into this Agreement and to perform its obligations hereunder.

8.2. This Agreement has each been duly authorized, executed and delivered by GVC and is a legal, valid and binding obligation of GVC.

8.3. GVC has the right to enter into this Agreement and to receive from ANESIVA the licensing arrangements outlined herein.

8.4. The execution and delivery of this Agreement do not conflict with or violate any requirement of applicable Laws or regulations.

## **9. Notification of Side-Effects and Regulatory Requirements**

9.1. GVC and ANESIVA shall comply with the terms and conditions of the Pharmacovigilance Agreement, which shall comply with the Adverse Event Reporting Requirements and shall be finalized within [ninety (90) days] after signing this License and Distribution Agreement.

9.2. In accordance with procedures to be mutually agreed between the Parties and which address the Laws and regulations of the Territory; both ANESIVA and GVC shall promptly appraise each other of any Serious Adverse Events occurring as a result of the use of the Product in order to comply with ICH requirements for reports of such events in each respective licensing territory.

9.3. In the event either Party believes it may be necessary to conduct a recall, field correction, market withdrawal, stock recovery, or other similar action with respect to any Product which were sold by ANESIVA or its Affiliates to GVC or its Affiliates under this Agreement (a "Recall"), ANESIVA and GVC shall consult with each other as to how best to proceed, it being understood and agreed that the final decision as to any Recall of any Product shall be made by ANESIVA; provided, however, that GVC shall not be prohibited hereunder from taking any action that it is required to take by applicable Laws. GVC and ANESIVA shall work together to mutually agree on the details of any Recall decision; however GVC is responsible for executing a Recall of

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GVC distributed Product. ANESIVA QA is responsible for notifying GVC QA of all quarantined Product related to Recall in ANESIVA's possession. If a Recall arises from the manufacture of the Product or ANESIVA's breach of its representations, warranties, including but not limited to the ANESIVA Warrants herein or obligations hereunder, the cost of goods sold, distribution expenses and third-Party recall expenses (collectively, the "Recall Costs") shall be [borne by ANESIVA]. If a Recall arises from GVC's acts or omissions in the marketing, distribution, storage or handling of such Product, Recall Costs shall be [borne by GVC]. GVC shall maintain records of all sales of Product and customers sufficient to adequately administer a Recall for the period required by applicable Laws.

## **10. Confidentiality and Public Disclosure**

10.1. The Parties expressly agree that their previously executed Confidential Disclosure Agreement ("CDA") [dated January 8, 2008], is made a part hereof by reference and that all terms, conditions and provisions of the original CDA, unless specifically modified herein, are to apply to this Agreement and are made a part of this Agreement as though expressly included; provided, however, the CDA shall be extended in duration for the period ending with the expiration or sooner termination of this Agreement or until it expires as set forth in the CDA, whichever term is longer.

10.2. Except for such disclosure as is deemed necessary, in the reasonable judgment of a Party, to comply with applicable Laws, no announcement, news release, public statement, publication, or presentation relating to the existence of this Agreement, the subject matter hereof, or either Party's performance hereunder will be made without the other Party's prior written approval, which approval shall not be unreasonably withheld. The Parties agree that they will use reasonable efforts to coordinate the initial announcement or press release relating to the existence of this Agreement.

10.3. Neither Party shall be required to seek the approval of the other Party to repeat any information regarding the terms of this Agreement that has already been publicly disclosed by such Party, or by the other Party, in accordance with Section §10.1, provided that such information remains accurate and complete.

## **11. Termination**

11.1. ANESIVA shall have the right to terminate this Agreement, without prejudice to the enforcement of any other legal right or remedy, immediately in the event of the default in the due and punctual payment of any amount payable under this Agreement by GVC to ANESIVA when and as same shall become due and payable, and such default shall continue for a period of [ninety (90) days] after written notice thereof has been given to GVC.

11.2. Notwithstanding any other termination rights set forth in this Agreement, either Party shall be entitled at any time, by written notice to the other, to terminate this Agreement immediately if the other Party commits or permits a material breach or default of any of the

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provisions of this Agreement and fails to remedy or cure such breach or default within [ninety (90) days] after receipt of written notice by the non-breaching Party.

11.3. ANESIVA may prematurely terminate this Agreement with at least [ninety (90) days] prior notice in writing with respect to the Territory if the Product sales are [less than either 40%] of the annual forecasted unit sales in provision or if the Product sales are [less than two million dollars United States Dollars (US\$2.0M) annually] in [local sales] at least [three (3) years] after [Market Authorization].

11.4. Either Party shall be entitled at any time, by written notice to the other, to terminate this Agreement immediately if (i) the other Party makes an assignment for the benefit of its creditors; (ii) the other Party is adjudicated bankrupt or becomes voluntarily or involuntarily subject to any proceedings for the benefit of its creditors, or (iii) a receiver of the property of the other Party is appointed or if any judgment or execution against it or its property remains unsatisfied for such period which would permit its property or any substantial part thereof to be sold.

11.5. Upon termination of this Agreement for any reason, the following shall apply:

(a) GVC shall immediately cease marketing and selling the Product in the Territory, the use of the Methods and Technical Know-How and the Proprietary Marks

(b) GVC shall have no further rights to market or sell, directly or indirectly, the Product;

(c) GVC shall forthwith deliver to ANESIVA original copies of all documents and records in its possession in connection with regulatory approvals applied for or obtained in the Territory referred to in §2.5;

(d) GVC shall return or destroy, at ANESIVA's discretion, any unsold Product, or if permitted by ANESIVA, GVC may sell all Product held in inventory or in the process of production at the time of such expiration or termination, provided that GVC shall pay to ANESIVA all amounts which would have been required to be paid under this Agreement through the date of final sale of all Product.

11.6. All in-Territory Product licenses, registrations or Marketing Authorizations will be transferred to ANESIVA if these are held in the name of GVC, its designates, importers or promoters where allowed by Law at the sole cost and expenses of ANESIVA necessary to accomplish any such transfer or transfers as the case may be.

11.7. The Parties agree that this Agreement may be assigned to any successor corporations with the prior written permission of the other Party, which permission shall not reasonably be withheld.

11.8. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination and the provisions of §9.3 as it pertains

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to Recalls, §11.6 as it pertains to transfer of the Marketing Authorizations, §10, §11.8, §14, §15 and §16 through §25 shall survive any expiration or termination of this Agreement.

## **12. Sales Training and [Training Devices]:**

12.1. Whenever possible, representatives of GVC may attend a regularly scheduled ANESIVA training session and be certified to train GVC sales representatives to demonstrate, market, and sell the Product. In the event that attendance at such a training session is not possible, an ANESIVA representative will train the GVC trainer at a mutually convenient time and place. ANESIVA will provide GVC copies of training materials for training at GVC facilities.

12.2. [Zingo training devices] can be [purchased at cost] by GVC. Such [training devices] will exclusively be used to generate sales from customers through local clinical evaluations and will not be sold under any circumstances. At [six (6) months] prior to an anticipated launch, GVC will provide ANESIVA with the first [twelve (12) month non-binding] rolling forecast of [trainers] from launch date.

12.3. The label and instructions on the [Zingo Training Device] shall be in English language only at delivery and GVC may re-label the [devices] according to the customs and laws of the Territory.

## **13. Marketing:**

13.1. GVC shall [use Commercially Reasonable efforts] in the [marketing] and [selling] of the Product throughout the Territory during the [Initial Term] of [this Agreement] and [any Renewal Term] or [Terms] thereof. During the term of any licensing agreement GVC will commit to providing a [commercially reasonable level] of resources of the Product to customers who may reasonably be expected to purchase or recommend the purchase of any of the Product.

13.2. GVC shall send to ANESIVA, upon ANESIVA's request no more frequently than [two (2) times] in any [Marketing Year], a brief summary of the most important promotional activities connected with the Product, the activities of GVC's sales forces in promoting the Product, including information relating to market developments and acceptance of the Product in the Territory.

13.3. ANESIVA will provide [reasonable number] of [sample copies] of any [materials, case studies, or papers] used in the United States of America to market, promote or sell any the Product.

13.4. Should GVC elect to use any of the [marketing materials] prepared for the United States market without modification [(e.g., clinical study reprints, models, posters, etc.)], ANESIVA will assist GVC in obtaining a [Commercially Reasonable quantity] of such [marketing materials] from current vendors. Any costs incurred to obtain these marketing materials will be [borne by GVC].

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13.5. ANESIVA will also provide [electronic copies] of any [photos, images, logos or the like] used to [market, sell or promote] the Product so GVC can maintain a [consistent global image] for the Product. The cost for any [marketing materials] generated from these [images] will be [borne by GVC].

(a) GVC represents and warrants that any locally produced marketing materials will fully comply with any Territory Law or Territory Regulatory Authority regulation in all respects, market and sell the Product in accordance with applicable Laws of the Territory, including, without limitation, in accordance with any certification required by a legislated or regulatory body, if applicable; and

(b) GVC shall comply with all Laws and regulations in any applicable country with jurisdiction over the Parties or with jurisdiction over the subject matter of this Agreement, including but not limited to, if applicable, the Laws of Qatar, United States of America and/or any applicable Laws in the Territory relating to the marketing and sale of the Product within the Territory and to obtain any and all required permits, certificates and licenses in connection with the foregoing.

(c) Any changes or amendments to Product packaging must be approved in advance by GVC and ANESIVA by mutual agreement.

13.6. GVC shall refrain from directly or indirectly selling the Product outside of the Territory during the term of this Agreement; and

13.7. GVC shall not [distribute, sell, market, or promote] any [topical, local anesthetic] (other than the Product) during the Term.

13.8. GVC acknowledges and agrees that the implementation of this Agreement requires the co-operation of both Parties and that the ability of each Party to carry out its obligations hereunder shall be dependent upon the other Party performing its obligations (including its responsibilities pursuant to the Quality Assurance Agreement, and the Pharmacovigilance Agreement).

#### **14. Insurance**

14.1. ANESIVA shall, at its sole cost and expense, take out and keep in full force and effect throughout the term of this Agreement and any renewal thereof, such insurance coverage, including but not limited to Product liability insurance coverage, in an amount that is customary in the pharmaceutical industry. All costs in connection with the placing and maintaining of such insurance coverage shall be borne solely by ANESIVA.

14.2. GVC shall take out and keep in full force and effect for the term of this Agreement and any renewal thereof, such insurance coverage as required by Laws in the Territory protecting against loss or damage occurring in connection with the local negligent handling and negligent sale of the Product in the Territory. All costs in connection with the placing and maintaining of

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such local insurance coverage in the Territory shall be borne solely by GVC, at the sole discretion of GVC.

14.3. Copies of all policies or certificates of insurance and any renewals thereof, shall be delivered promptly to ANESIVA by GVC from time to time throughout the term of this Agreement and any renewal thereof

## **15. Indemnification and Liability**

15.1. GVC shall defend, indemnify and hold harmless ANESIVA from and against all losses, liabilities and expenses (including reasonable attorneys' fees) for personal injury or property damage to a third Party arising out of the use of the Product marketed by GVC, its affiliates insofar as any such claim for loss, liability and expense is based upon negligence of GVC, its affiliates in the handling and marketing of such Product. ANESIVA shall give GVC prompt written notice of any such claim. GVC shall be entitled to assume complete control of the defense of such claim. ANESIVA shall render such assistance to GVC as may be reasonably requested by GVC and GVC shall reimburse ANESIVA for its reasonable out-of-pocket expenses incurred in rendering such assistance.

15.2. ANESIVA shall defend, indemnify and hold harmless GVC from and against all losses, liabilities and expenses (including reasonable attorneys' fees) for (i) personal injury or damage arising out of the use of the Product, provided the claim for such loss, liability and expense is based upon product liability or negligence of ANESIVA, its affiliates, subsidiaries or licensees in the Specifications, the Methods and Technical Know-How, Improvements, manufacture or marketing of such Product or (ii) any suit or proceeding brought against GVC insofar as such suit or proceeding is based on a claim that the Methods and Technical Know-How and Improvements to any Product (save to the extent that the Product concerned, or any part thereof, has been developed as a result of additional technology methods or compositions of GVC) constitutes an infringement of any patent, copyright, trade secret or other intellectual property right of any person other than ANESIVA or GVC. For greater certainty, in no event shall ANESIVA have any liability (whether direct or indirect, in contract or tort or otherwise) to GVC or any other person asserting claims on behalf of or in right of GVC hereunder which have resulted primarily from the negligence or wilful misconduct of GVC or its representatives. GVC shall give ANESIVA prompt written notice of any such claim. ANESIVA shall be entitled to assume complete control of the defense of such claim. GVC shall render such assistance to ANESIVA as may be reasonably requested by ANESIVA and ANESIVA shall reimburse GVC for its reasonable out-of-pocket expenses incurred in rendering such assistance.

## **16. Force Majeure**

The Parties hereto shall not be liable for any damage if the performance of all or parts of this Agreement is hindered or prevented by causes beyond the performing Party's control and without its fault or negligence, including but not limited to acts of God or of public enemy, nuclear incidents, acts, Laws, orders or regulations of any Government Regulatory Authority or department or agency thereof acting in either its sovereign or contractual capacity, fires, floods,

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epidemics, earthquakes and other natural disasters, quarantine restrictions, strikes, work stoppages, slowdowns or other job actions, freight embargoes, shortages of fuel or other items, delays in transportation, boycotts, unusually severe weather and riots, insurrections, revolutions, wars or other civil or military disturbances.

# **17. Entire Agreement**

This Agreement constitutes the entire agreement between the Parties hereto with respect to the subject-matter herein contained, and its execution has not been induced by, nor do either of the Parties hereto rely upon or regard as material, any representations or writings whatsoever not incorporated herein and made a part hereof. This Agreement shall not be amended, altered or qualified except by an instrument in writing, signed by each of the Parties hereto and any amendments; alterations or qualifications hereof shall not be binding upon or affect the rights of any Party who has not given its consent as aforesaid. All previous agreements or arrangements between the Parties, written or oral, relating to the subject matter hereof are hereby cancelled and superseded, except for the Confidentiality Agreement [dated as of January 8, 2008] between the Parties.

# **18. Counterparts**

This Agreement may be executed by the Parties in separate counterparts each of which when so executed and delivered in original form or by facsimile transmission shall be an original, but all such counterparts shall together constitute one and the same instrument, and shall be equally valid and binding on the Parties.

# **19. Notices**

All notices, requests, demands or other communications made by the terms hereof required or permitted to be given by one Party to the other shall be given in writing by personal delivery or by facsimile transmission, addressed to such other Party or delivered to such other Party as follows:

## **If to GREEN VISION COMPANY:**

Green Vision Company  
Attention: Business Development &  
Marketing Department  
Al Azizya  
P.O Box 55272  
Doha, Qatar  
Tel: +974 4517815  
Fax: +974 4517247

## **If to ANESIVA:**

Anesiva, Inc.  
Attention: General Counsel  
  
650 Gateway Boulevard  
South San Francisco, CA 94080  
Tel: 650-624-9600  
Fax: 650-624-7540

or to such other address as the addressee may have specified by a notice given under this provision. Any such notice or other communication shall be deemed to have been given when received and, if sent by facsimile transmission, shall be deemed to have been given when the appropriate answerback is received.

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## **20. Severability**

Should any of the provisions of this Agreement be or become unenforceable or invalid for any reason whatsoever, such unenforceability or invalidity shall not affect the enforceability or validity of the remaining provisions of the Agreement and such unenforceable or invalid portion shall be severable from the remainder of this Agreement.

## **21. Waiver**

The failure at any time to require performance of any provision of this Agreement shall not affect the full right to require performance at any later time. The waiver of a breach of any provision of this Agreement shall not constitute a waiver of the provision or of any succeeding breach.

## **22. No Assignment and Permitted Assignment.**

22.1. Neither Party shall, without the prior written consent (not to be unreasonably withheld or delayed) of the other Party having been obtained, assign or transfer this Agreement to any person or entity, in whole or in part, provided that, each Party may assign or transfer this Agreement to any Affiliate or to any successor by merger of such Party, or upon a sale of all or substantially all of such Parties assets, provided that such assigning Party shall remain liable for its obligations hereunder.

22.2. All of the terms and provisions of this Agreement shall be binding upon and inure to the benefit of and be enforceable by the Parties hereto and their respective successors and assigns.

## **23. Partnership, Agency Denied**

This Agreement does not and shall not be construed to create any partnership, joint venture or agency whatsoever as between the Parties and neither Party shall, by reason of any provision herein contained, be deemed to be the partner, joint venturer, agent or legal representative of the other nor shall either have the ability, right or authority to assume or create, in writing or otherwise, any obligation of any kind, express or implied, in the name of or on behalf of the other Party.

## **24. Headings**

The division of this Agreement into articles and sections is for convenience of reference only and shall not affect the interpretation or construction of this Agreement

## **25. Currency**

Except as specifically noted otherwise, all monetary amounts stated in this Agreement are expressed in United States Dollars.

## **26. Applicable Law/Jurisdiction**

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26.1. This Agreement is construed in accordance with and shall exclusively be governed by the Laws of [the State of Delaware] in [the United States of America].

26.2. All disputes arising out of or relating to this Agreement shall be submitted to the exclusive jurisdiction of the appropriate courts of [Delaware] in [the United States of America].

26.3. All trade terms used in this Agreement shall be interpreted in accordance with INCOTERMS 2000 (International Rules for Interpretation of Trade Terms, International Chamber of Commerce, Publ. 560, 1999).

**27. Singular and Plural Forms**

The use herein of the singular form shall also denote the plural form, and the use herein of the plural form shall denote the singular form, as in each case the context may require.

**28. English Language**

The Parties hereto have required that this Agreement and all documents and notices relating hereto be drawn up in the English language.

**IN WITNESS WHEREOF**, the Parties hereto have caused this Agreement to be executed in duplicate, as of the Effective Date, by their duly authorized representatives.

**READ AND ACCEPTED BY:**

**ANESIVA INC.**

Per: /s/ Samantha Miller

Name: Samantha Miller M.S.c, MBA

Title: VP Business Development.

Date: \_\_\_\_\_

**READ AND ACCEPTED BY:**

**GREEN VISION COMPANY**

Per: /s/ Amer A. Salameh

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Name: Amer A. Salameh B.Sc. Pharmacy

Title: Managing Partner  
Business Development &  
Marketing.

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