

18-02718-E

February 22, 2018

Dear SEC FOIA Office:

I am requesting a copy of

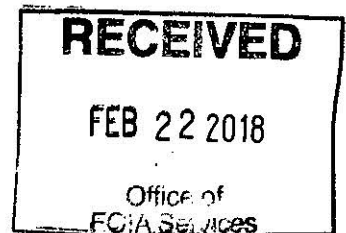
Exhibit 10.17 to Form 10-Q filed by AEROGEN INC on 11/14/2003.

I am willing to pay up to \$61.00.

Thank you,

Diane Martin

AUS Consultants Inc.
155 Gaither Dr, Suite A
Mt. Laurel
NJ 08054
856.234.9200





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

Office of FOIA Services

March 28, 2018

Ms. Diane Martin
AUS Consultants, Inc.
155 Gaither Dr., Suite A
Mt. Laurel, NJ 08054

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-02718-E

Dear Ms. Martin:

This letter is in response to your request, dated and received in this office on February 22, 2018, for Exhibit 10.17 to Form 10-Q filed by Aerogen, Inc. on November 14, 2003.

The search for responsive records has resulted in the retrieval of 62 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 morrowa@sec.gov or (202) 551-8376. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Jeffery Ovall 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 or via e-mail at ogis@nara.gov.

Sincerely,

A handwritten signature in cursive script that reads "Alysia Morrow".

Alysia Morrow
FOIA Research Specialist

Enclosure

DISTRIBUTION, MANUFACTURING AND SUPPLY AGREEMENT

THIS DISTRIBUTION, MANUFACTURING AND SUPPLY AGREEMENT (the "Agreement") is made and entered into as of September 30, 2003 (the "Effective Date") by and between AEROGEN, INC., a Delaware corporation, with offices at 2071 Stierlin Court, Mountain View, CA 94043 ("Aerogen"), and MEDICAL INDUSTRIES AMERICA, INC., an Iowa corporation, with offices at 2636 289th Place, Adel, IA 50003 ("MIA"). Aerogen and MIA may be referred to herein individually as a "Party" or collectively as the "Parties".

BACKGROUND

WHEREAS, Aerogen has designed and developed a proprietary, open-cup, continuous-flow, general-purpose portable nebulizer and desires to have MIA manufacture and distribute that product for use by customers solely in the home or in alternate care facilities;

WHEREAS, MIA is engaged in the manufacture, distribution and sale of medical products and desires to obtain such rights to manufacture and distribute Aerogen's nebulizer product; and

WHEREAS, the Parties also desire to provide terms under which Aerogen will supply to MIA, or allow MIA to manufacture, a key component of the Aerogen nebulizer product.

NOW, THEREFORE, in consideration of the foregoing premises and the covenants contained herein, the Parties hereby agree as follows:

AGREEMENT

1. DEFINITIONS.

In addition to the terms defined in the other provisions of this Agreement, the following capitalized terms shall have the meanings indicated for purposes of this Agreement:

1.1 "Aerogen Patents" means all patents and patent applications that are Controlled by Aerogen during the Term and that claim the Product. The Aerogen Patents as of the Effective Date are listed on *Exhibit K*.

1.2 "Aerogen Licensed Rights" means the claims within the Aerogen Patents that specifically claim the Product and the Aerogen Technology.

1.3 "Aerogen Technology" means proprietary trade secrets, know-how, techniques, methods, technical specifications, and test data that are Controlled by Aerogen and are necessary or useful for the manufacture or marketing of the Product.

1.4 "Affiliate" means, with respect to a Party, any natural person, company or entity controlled by, controlling, or under common control with such Party. As used in this **Section 1.4**, the term "controlling" (with correlative meanings for the terms "controlled by" and "under common control with") means possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of the controlled entity, whether by ownership of a majority of the voting securities of such entity, by contract, or otherwise.

1.5 "Approval Date" means the first day of the first month after the date upon which 510(k) marketing clearance is first obtained for the Product in the United States.

1.6 "Confidential Information" means any information deemed by a Party to be its confidential or proprietary information that it discloses to the other Party under this Agreement and marks as "confidential" or the equivalent at the time of disclosure, which may include, without limitation, engineering designs and drawings, know-how, trade secrets, research data, processes, techniques, research projects, work in process, future developments, and any scientific, manufacturing, marketing, business plan, financial or personnel matters relating to a Party or its present or future products, sales, suppliers, customers and patients, employees, investors or business. Any "Confidential Information" as defined in the Letter Agreement dated February 25, 2003 between the Parties and exchanged pursuant thereto, shall be deemed to be Confidential Information for purposes of this Agreement.

1.7 "Controlled" means, with respect to particular information or intellectual property, that the applicable Party owns or has a license to such information or intellectual property and has the right to grant to the other Party access and a license to such information or intellectual property as provided in this Agreement without violating any obligations to any third party.

1.8 "Cost of Goods" means MIA's actual direct costs associated with the manufacturing and assembling of the Product, to include: materials and labor, and reasonable overhead and administrative costs to the extent directly allocable to such manufacturing activity of such Products (such as ordering process, collections, and account maintenance for those Products), and shipping.

1.9 "FDA" means the United States Food and Drug Administration, and any successor thereto.

1.10 "Financing Event" means either (a) a merger or combination after which the combined entity has not less than twelve million dollars (\$12,000,000) in cash post closing or (b) guaranteed financing (contractual obligations to provide funding) to Aerogen after August 25, 2003 of not less than twelve million dollars (\$12,000,000) in cumulative gross proceeds (excluding amounts paid by MIA pursuant to **Sections 5.3 and 5.5**), including without limitation through the sale of equity, debt financing, the sale or grant of rights to assets, grant of product rights or any combination thereof.

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1.11 “Gross Selling Price” means, on a country-by-country basis, the actual, bona fide gross selling price, before term discounts, at which MIA or its Affiliate (or a Related Sub-Distributor, if applicable) sells or otherwise markets Product, including Product components and Product accessories, to sub-distributors and to end users in such country; *provided, however*, that the Gross Selling Price for transfers from MIA to a Related Sub-Distributor shall be the greater of (i) the actual, bona fide gross selling price, before discounts, by such Related Sub-Distributor to an unaffiliated third party, or (ii) the fair market value, based on arms-length sales, of Product, including Product components and Product accessories. If MIA sells the Product at more than one gross selling price in a given country within the Territory, the Gross Selling Price in such country with respect to Product shall mean the total revenue at such bona fide gross selling prices, in the relevant Sales Quarterly accounting period, divided by the number of Products sold in that period in such country. No Gross Selling Price shall be assessed on units of Product transferred free of charge by MIA to sub-distributors solely for use for marketing purposes and not for resale. The Gross Selling Price for Product sold in combination or bundled with other products shall be determined on a country-by-country basis as follows:

(a) If the Product and each of the other products in the combination or bundle are sold separately in such country, the Gross Selling Price shall be calculated by multiplying the gross selling price of the combination or bundle by the fraction $A/(A+B)$ where A is the average Gross Selling Price of Product when sold separately, and B is the gross selling price of the other product(s) in the combination or bundle.

(b) If each of the other products in the combination or bundle are not sold separately in such country, but the Product is sold separately in such country, the Gross Selling Price shall be calculated by multiplying the gross selling price of the combination or bundle by the fraction A/C where A is the Gross Selling Price of the Product when sold separately, and C is the gross selling price of the combination or bundle.

(c) If the Product is not sold separately in such country, Gross Selling Price shall be calculated by multiplying the gross selling price of the combination or bundle by the fraction $D/(D+E)$, where D is the fair market value of the Product and E is the fair market value of the other product(s) in the combination or bundle, as such fair market values are determined in good faith by the Parties.

1.12 “Manufacturing Improvements” has the meaning set forth in **Section 3.4(a)**.

1.13 “OnQ Aerosol Generator” means Aerogen’s proprietary aerosol generator, as described in *Exhibit A*.

1.14 “OnQ Aerosol Generator Manufacturing Facility” means the facility at which manufacture and assembly of OnQ Aerosol Generators is conducted, which shall either be the facility being used as of the Effective Date, or such other location and facility as established by mutual agreement of the Parties pursuant to **Section 3.8**.

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1.15 “OnQ Manufacturing Period” means that period of time commencing on the Effective Date and ending upon the exercise by Aerogen of its Repurchase Option.

1.16 “Product” means Aerogen’s proprietary Aeroneb® Go open-cup, continuous-flow, general-purpose portable nebulizer, and described on *Exhibit B*, incorporating the OnQ Aerosol Generator, and including any Product Improvement incorporated therein.

1.17 “Product Improvement” means, on a country-by-country basis, any modification or line extension of the Product, or accessory that is designed for use with the Product, that: (a) is developed by Aerogen, or by MIA as permitted in **Section 3.4(a)**; and (b) does not require any separate 510(k) marketing clearance, Premarket approval (PMA) application, Biologics License Application (BLA), or New Drug Application (NDA) regulatory filing or approval, or any foreign equivalent thereto, to promote, market and sell a Product containing such modification or line extension or accessory in the Territory.

1.18 “Related Sub-Distributor” means any distributor (or similar entity) (a) to which MIA (or its Affiliate) sells or otherwise transfers Products for resale or redistribution, and (b) with which MIA or any Affiliate of MIA has any direct or indirect financial relationship (which may include, without limitation, equity ownership, credit facilities, rebates, profit or revenue interest, etc.).

1.19 “Regulatory Agency” means any national, supranational, regional, state, provincial or local regulatory agency or other governmental entity that has authority, responsibility or jurisdiction with regard to the manufacture, marketing and sale of the Product within the Territory.

1.20 “Repurchase Option” has the meaning set forth in **Section 3.8(f)**.

1.21 “Sales Quarter” means a period of three (3) successive calendar months commencing on the later of (a) the first day of the first full month following delivery of ~~[the first ten thousand (10,000)]~~ OnQ Aerosol Generators or (b) the Approval Date, and each three (3) successive calendar month period thereafter during the Term.

1.22 “Sales Year” means the period of twelve (12) successive calendar months commencing on the later of (a) the first day of the first full month following delivery of ~~[the first ten thousand (10,000)]~~ OnQ Aerosol Generators or (b) the Approval Date, and each successive twelve (12) month period thereafter during the Term.

1.23 “Specifications” means the technical and performance specifications for the OnQ Aerosol Generators or the Product, as may be amended from time to time to incorporate any improvements, modifications, changes or revisions thereto. The Specifications for the OnQ Aerosol Generator are attached as *Exhibit A*, and the Specifications for the Product are attached as *Exhibit B*.

1.24 "Supply Quarter" means a period of three (3) successive calendar months commencing on the later of (a) the first day of the first full month following delivery of [the first thirty thousand (30,000)] OnQ Aerosol Generators or (b) the Approval Date, and each three (3) successive calendar month period thereafter during the Term.

1.25 "Term" means the term of this Agreement, more fully described in **Section 13.1**.

1.26 "Territory" means those countries identified on *Exhibit C*, as may be amended by the Parties pursuant to **Section 2.4**.

1.27 "Trademarks" shall mean those trademarks and trade names of Aerogen that Aerogen from time to time during the Term deems appropriate for use in connection with the marketing and sale of the Product, the current versions of which are listed on *Exhibit D*. Jointly developed or applied-for trademarks and/or trade names pursuant to **Section 8.1** shall be considered Trademarks.

2. DISTRIBUTION RIGHTS.

2.1 Distribution Rights. Subject to the terms of this Agreement, Aerogen hereby appoints MIA as its distributor during the Term to market, promote, distribute and sell the Product in the Territory: (a) on an exclusive basis solely for use in the home-based, open-cup, continuous-flow, general-purpose nebulizer market (e.g., not for use in hospitals); and (b) on a non-exclusive basis solely for use in alternate care facilities. Subject to the terms of **Section 2.2** and **Section 5.2**, MIA may appoint sub-distributors in the Territory subject to approval by Aerogen, which approval shall not be unreasonably withheld. Subject to the terms of the Agreement, Aerogen hereby grants to MIA during the Term the royalty-bearing, non-transferable right and license under the Aerogen Licensed Rights to import, export, offer for sale and sell the Product in the Territory solely for use by end users in the home-based, open-cup, continuous-flow, general purpose nebulizer market and in alternate care facilities.

2.2 Sub-Distributor Obligation. In order for MIA to retain distribution rights in each Expansion Country of the Territory (as defined in *Exhibit C*), MIA shall complete and present to Aerogen a definitive business plan, including a distribution strategy with either intent to contract or hire sales representatives, or a letter of intent and a draft definitive agreement with a sub-distributor, in each such Expansion Country within the first six (6) months following the Effective Date. The business terms of each such agreement shall be subject to approval by Aerogen. At any time during such six (6) month period, MIA may elect to terminate the Agreement with respect to any Expansion Country, which will result in a commensurate reduction of the minimum royalties and Product System (as Systems are defined on *Exhibit A*) sales requirements attributable to such country as reflected in *Exhibit I* and *Exhibit J*; provided, however, that the aggregate minimum Product System sales requirements for Europe in its entirety (as defined in *Exhibit J*) shall remain unchanged and the minimums for the remaining individual European countries adjusted as mutually agreed upon by the Parties. If as to any particular Expansion Country, MIA has not met the preceding requirements of this section by the end of such six (6) month period, then Aerogen may thereafter terminate MIA's rights under this

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Agreement with respect to such country, by written notice, and on such termination such country shall no longer be in the Territory and all rights in such country shall revert exclusively to Aerogen. MIA will provide Aerogen with written notice regarding any direct or indirect financial affiliation that arises between MIA (or any of its Affiliates) and any of its existing or proposed sub-distributors during the Term, with such notice to be given promptly upon the commencement of negotiations with a sub-distributor involving any financial interest (including, but not limited to, equity ownership, credit facilities, rebates, profit or revenue interest, etc.), with full details of the final relationship to be provided to Aerogen upon final deal closure. MIA shall require that any Related Sub-Distributors make complete and accurate reports to MIA in writing on a quarterly basis of all Gross Selling Prices for Products sold or otherwise transferred by such Related Sub-Distributor, and Aerogen shall have the right to inspect and audit all such reports pursuant to **Section 5.7**.

2.3 No Conflicts.

(a) Notwithstanding any term or provision of this Agreement, Aerogen retains the right to develop and/or commercialize products for use in hospitals, alternate care facilities, and any other use, and products for home-based use other than the Product; *provided, however*, that during the Term, other than through MIA, Aerogen agrees not to introduce in the Territory, nor grant to any third party the right to introduce in the Territory, any open-cup, continuous-flow, general-purpose nebulizer for home-based use incorporating the OnQ Aerosol Generator.

(b) During the Term, MIA agrees that neither it nor its Affiliates or sub-distributors will develop, market or distribute in the Territory, either directly or through a third party, any products (other than the Product) that contain an aerosol generator utilizing a vibrating element that would directly compete with or otherwise reduce the sales of the Product.

(c) MIA covenants that it and its Affiliates and sub-distributors shall not market, promote, distribute or sell the Product for any use other than home-based use or use in an alternate care facility.

2.4 Right of First Negotiation to Expand the Territory. During the Term, but no sooner than six (6) months from the Effective Date, MIA shall have a right of first negotiation to obtain rights to distribute the Product in a country that is not listed on *Exhibit C*. MIA shall notify Aerogen of its intent in writing, and, if the marketing rights for the Product in such country are available for licensing to MIA, then the Parties shall negotiate in good faith to reach an agreement regarding the expansion of the Territory to include such country. If the Parties reach agreement on the expansion of the Territory, *Exhibit C* shall be amended to reflect the additional country(ies) in which MIA may distribute the Product pursuant to this Agreement.

3. PRODUCT MANUFACTURE.

3.1 Product Manufacturing License. Subject to the terms of this Agreement, Aerogen hereby grants to MIA during the Term, the non-transferable license (without the right to grant sublicenses, except to subcontractors and/or vendors that fabricate and/or supply

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components of the Product on behalf of MIA as shall be mutually agreed to from time to time) under the Aerogen Licensed Rights and the Manufacturing Improvements to manufacture and assemble components of the Product (excluding the OnQ Aerosol Generator) and to assemble final Product for distribution and sale in the Territory as permitted under **Section 2.1**.

3.2 Manufacture of Product. MIA shall be responsible for manufacturing all of its (and its sub-distributors') requirements for the Product (excluding the OnQ Aerosol Generator component, which shall be supplied by Aerogen as provided in this Agreement), in order to meet on a timely basis all market demand therefore. With respect to such manufacturing, MIA shall: (a) manufacture, assemble and distribute the Product in accordance with the Quality System Regulations; (b) maintain certification to current, applicable EN/ISO standards and any future amendments; (c) maintain certification compliant with all European regulations and directives applicable to the manufacture of medical devices; and (d) comply with applicable requirements of any other Regulatory Agencies having jurisdiction over the development, manufacture, testing or use of the Product. MIA shall, at its own expense, obtain and maintain the necessary licenses and permits required to manufacture and distribute the Product in accordance with this Agreement.

3.3 Product Quality. At Aerogen's request, MIA shall provide Aerogen samples of the Product being manufactured and distributed by MIA (or its Affiliates or sub-distributors), for inspection by Aerogen to assure that the quality of such Product meets with Aerogen's approval, not to be unreasonably withheld. If Aerogen determines that any such Product sample is deficient (e.g., because such Product or its packaging does not meet the applicable Product Specifications or quality of manufacture), then Aerogen may give MIA written notice of such deficiencies, and MIA shall promptly thereafter remedy such deficiencies to Aerogen's reasonable satisfaction.

3.4 Product Modifications.

(a) MIA may make manufacturing changes to the Product for the purpose of reducing Product manufacture and assembly costs ("**Manufacturing Improvements**"), subject to Aerogen's written consent, which shall not be unreasonably withheld. All such Manufacturing Improvements shall be disclosed to Aerogen in writing. MIA will make no changes to the OnQ Aerosol Generator. If MIA desires to make any other changes to the Product or any components thereof, MIA shall first request the right to make such changes, and such proposed changes shall be discussed with Aerogen and shall not be made without Aerogen's prior written consent. If any changes are agreed upon, they will be made, either (i) by MIA at MIA's expense or (ii) by Aerogen, with Aerogen's activities to be reimbursed by MIA. For clarity, the only changes or modifications that MIA may make that relate to the Product or its manufacture are changes that would qualify as Product Improvements, Manufacturing Improvements, or cost reductions, and any such changes or modifications require Aerogen's prior written consent as provided above.

(b) Nothing in the Agreement, other than the restrictions described in **Section 2.3(b)**, will prevent MIA from continuing to develop and commercialize products for the home market in the respiratory field separate from the Product or from making any

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Manufacturing Improvements to the Product as permitted by subclause (a) above, (but no such development will negate or limit MIA's obligation to make minimum purchases as provided in **Section 6.1**); *provided, however*, MIA will have no right to use the OnQ Aerosol Generator or any Aerogen Licensed Rights in connection with any such activities. Subject to the foregoing, MIA will be free to use any inventions MIA may make outside the scope of the Agreement in such other products.

3.5 [Nebule Interfit] Arrangement. Aerogen agrees to work with MIA in good faith to devise a work plan for the development and regulatory activities associated with a new product that would include [a proprietary device interfit with a customized nebule for use with either albuterol or ipratropium]. If a work plan is agreed upon, the Parties will negotiate in good faith an agreement for the development and commercialization of that new product. If no agreement is reached by August 31, 2004, then neither Party will have any further obligation to negotiate with the other concerning such a new product.

3.6 Quality Control Procedures. MIA shall maintain all documentation and quality control test results relating to the quality control procedures for each Product for a period of three (3) years after it delivers such Product to any sub-distributor or customer. During the Term, Aerogen may periodically review MIA's quality control program documentation, and may work with MIA to audit, survey, or verify the adherence of MIA to the quality control and to assess its compliance with the quality control procedures, and to discuss any related issues with MIA's manufacturing and management personnel.

3.7 OnQ Aerosol Generator Manufacturing. Other than as provided for during the OnQ Manufacturing Period in **Section 3.8** below, Aerogen will be solely responsible during the Term for the manufacture and supply to MIA of its requirements of the OnQ Aerosol Generator for incorporation into the Product, pursuant to the terms of **Article 4**. Aerogen will use reasonable efforts to time its production of OnQ Aerosol Generators so as to maintain in stock not less than the number of OnQ Aerosol Generators firm-ordered by MIA (in accordance with appropriate forecasts) for delivery within the next thirty (30) days, as provided in **Section 4.1**.

3.8 OnQ Manufacturing Period.

(a) **MIA Manufacturing.** During the OnQ Manufacturing Period, MIA shall have the right, but not the obligation, to manufacture, pursuant to the terms of this **Section 3.8**, all its requirements of OnQ Aerosol Generators for use in assembling Product for sale and distribution by MIA as permitted in **Section 2.1**. MIA shall comply with all applicable Aerogen Specifications and protocols for the OnQ Aerosol Generators it manufactures as disclosed by Aerogen as part of the Aerogen Technology.

(b) **OnQ Aerosol Generator Manufacturing License.** Aerogen hereby grants to MIA a non-exclusive, non-transferable license (without the right to grant sublicenses) under the Aerogen Technology to manufacture and assemble the OnQ Aerosol Generator at the OnQ Aerosol Generator Manufacturing Facility solely during the OnQ Manufacturing Period, and

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solely for use in assembling the Product that MIA is permitted to distribute and sell pursuant to **Section 2.1**, and for use by Aerogen pursuant to **Section 3.8(e)**.

(c) Equipment Sale. Upon Aerogen's receipt of the payments owed in **Section 5.1**, Aerogen sells and assigns to MIA Aerogen's entire right, title and interest in the equipment listed in *Exhibit E* (the "**Equipment**"). During the OnQ Manufacturing Period, the Equipment will continue to be housed at the OnQ Aerosol Generator Manufacturing Facility. Upon the Effective Date, MIA shall have the right to assume full authority over the manufacturing of the OnQ Aerosol Generator at the OnQ Aerosol Generator Manufacturing Facility in the event of Aerogen's non-performance under **Section 3.8(d)** that results in a failure to satisfy MIA's requirements for quantities of OnQ Aerosol Generators set forth in the forecasts and purchase orders provided by MIA in accordance with **Sections 4.1** and **4.2**, until expiration of the OnQ Manufacturing Period, including the authority to direct Aerogen as to the operational objectives to be achieved by the key manufacturing personnel to be provided by Aerogen pursuant to **Section 3.8(d)**, but subject to **Section 3.8(e)**. During the OnQ Manufacturing Period, MIA shall obtain and maintain all-risk insurance coverage with respect to the Equipment insuring against, among other things: casualty, including loss or damage due to fire and the risks normally included in extended coverage, malicious mischief and vandalism, for not less than the full replacement value of said Equipment.

(d) Contract Manufacturing Services. During the OnQ Manufacturing Period, Aerogen shall provide to MIA and MIA agrees to accept from Aerogen contract manufacturing services for the manufacture of MIA's requirements of OnQ Aerosol Generators (subject to the forecasts in *Exhibit F*) at the OnQ Aerosol Generator Manufacturing Facility using the Equipment (the "**Services**"). In connection with the Services, Aerogen shall: (i) provide and supervise appropriately trained personnel resources necessary to manufacture MIA's requirements of OnQ Aerosol Generators (but not to exceed that number of manufacturing personnel employed by Aerogen as of the Effective Date in conducting its manufacture of OnQ Aerosol Generators at the OnQ Aerosol Generator Manufacturing Facility at its location as of the Effective Date unless additional personnel are necessary to satisfy MIA's requirements for quantities of OnQ Aerosol Generators set forth in the forecasts and purchase orders provided by MIA in accordance with **Sections 4.1** and **4.2**); and (ii) maintain the Equipment at the OnQ Aerosol Generator Manufacturing Facility in good working condition; and (iii) if applicable, transfer manufacturing activities, including moving all Equipment, to the new location for the OnQ Aerosol Generator Manufacturing Facility, if such location is agreed to and secured by the Parties pursuant to **Section 3.9**. The methods, details and means of performing such services will be determined by Aerogen in its reasonable discretion. In connection with the Services, Aerogen will be solely responsible for all monthly expenses associated with the current OnQ Aerosol Generator Manufacturing Facility, including without limitation, all rents, taxes, equipment maintenance, payroll and employee benefit and insurance expenses, utilities, and phone charges. In the event of commencement of bankruptcy proceedings against Aerogen, MIA's right to access and use the Equipment, and to manufacture the OnQ Aerosol Generator shall not be limited, prohibited, or encumbered by Aerogen. The terms and conditions of **Article 4** shall apply to the order, purchase and delivery of OnQ Aerosol Generators manufactured by Aerogen

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pursuant to the Services. OnQ Aerosol Generators manufactured by Aerogen in the course of providing the Services shall meet the OnQ Aerosol Generator Specifications set forth in **Exhibit A** and shall be subject to the warranty set forth in **Section 9.4**.

(e) **Manufacturing Capacity.** It is understood and agreed that during the OnQ Manufacturing Period, production of OnQ Aerosol Generators shall include making OnQ Aerosol Generators required by MIA for use in MIA's assembly of the Product and also for use by Aerogen in making other Aerogen products and for Aerogen's research purposes (which estimated requirements are set forth in **Exhibit F**); *provided* that MIA is appropriately reimbursed, to the extent that MIA bears associated costs for such production.

(f) **Repurchase Option.** Following the earliest of (a) occurrence of a Financing Event, (b) any termination of the Agreement for any reason or (c) the first (1st) anniversary of the Effective Date provided that Aerogen has met its obligations under the Agreement up to and including that date, Aerogen shall have the right to repurchase the Equipment from MIA, and to simultaneously revoke and terminate the rights granted to MIA under **Section 3.8(a)**, (the "**Repurchase Option**"). Aerogen may exercise the Repurchase Option upon thirty (30) days written notice to MIA and including with such notice, delivery of evidence of the Financing Event, if applicable, and payment to MIA of one dollar (\$1.00) as consideration for the repurchase of the Equipment and the termination and revocation of rights. Within such thirty (30) day notice period, MIA shall sell and assign to Aerogen the entire right, title and interest in the Equipment, free and clear of any and all encumbrances, and shall take such action as reasonably requested by Aerogen to document and perfect such sale and assignment. MIA covenants that it shall not sell, lease, mortgage or otherwise encumber in any manner its interest in the Equipment.

3.9 Leasehold. Following the Effective Date, and provided that Aerogen terminates its obligations under the lease to the current OnQ Aerosol Generator Manufacturing Facility, Aerogen and MIA shall mutually negotiate with appropriate third parties in an effort to secure a new location for the OnQ Aerosol Generator Manufacturing Facility. The terms of such lease shall be mutually agreeable to both MIA and Aerogen. MIA shall sign as lessee of such leasehold, and Aerogen will be solely responsible for all monthly expenses associated with such new OnQ Aerosol Generator Manufacturing Facility, including without limitation, all rents, taxes, equipment maintenance, payroll, utilities, and phone charges. Aerogen agrees to sublease the facility from MIA on the same terms and conditions of said lease, upon the end of the OnQ Manufacturing Period, and MIA agrees to grant such sublease to Aerogen on such terms. If Aerogen does not terminate its obligations under the lease to the current OnQ Aerosol Generator Manufacturing Facility, it will provide for access by MIA to the OnQ Aerosol Generator Manufacturing Facility for a period of sixty (60) days, in the event of Aerogen's default under such lease.

3.10 Back-Up Manufacturing Right. Following the end of the OnQ Manufacturing Period, if at any time during the remainder of the Term, Aerogen (or its Affiliate or assignee, as applicable) either: (a) is not financially able to maintain the OnQ Aerosol Generator Manufacturing Facility, and therefore ceases operating such facility; or (b) fails to timely supply

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to MIA a material quantity of the OnQ Aerosol Generators ordered by MIA in accordance with the terms and conditions of **Article 4**, then MIA may, by written notice to Aerogen, require that Aerogen meet immediately with MIA to resolve the problem. In such case, the Parties shall discuss in good faith the issue and seek to achieve a resolution as soon as possible. If such resolution is not reached within sixty (60) days of such notice from MIA, and Aerogen has not by that date otherwise cured the problem and supply deficiency, then Aerogen shall grant to MIA a non-exclusive, non-transferable license (without the right to grant sublicenses) under the Aerogen Technology to manufacture and assemble the OnQ Aerosol Generator solely for MIA's use in assembling the Product for sale and distribution as permitted in **Section 2.1**, which license shall automatically terminate on the earlier of August 1, 2009, or termination of the Agreement by MIA or by Aerogen pursuant to **Article 13**.

4. ONQ AEROSOL GENERATOR FORECASTS, ORDERS AND DELIVERY.

4.1 Forecasts. On the first day of each calendar month during the Term, MIA shall provide to Aerogen a rolling forecast of MIA's anticipated OnQ Aerosol Generator purchases for the following ~~[twelve (12) month]~~ period. MIA shall provide each forecast to Aerogen thirty (30) days in advance of the beginning of the forecast period to which the forecast pertains. The ~~[first month]~~ of each such forecast shall constitute an order to buy the amount of OnQ Aerosol Generators listed in the forecast for such ~~[month]~~; the remaining ~~[eleven (11) months]~~ of each forecast will constitute a non-binding, good faith forecast. An initial forecast is shown on *Exhibit F*; the forecast shown in ~~[Months 1 through 3]~~ shall constitute a firm order by MIA for which MIA will promptly submit a purchase order to Aerogen on the Effective Date for at least the quantities indicated for such ~~[months]~~.

4.2 Purchase Orders. Each forecast shall be accompanied by a binding purchase order for ~~[the first month]~~ of the forecast period. The quantity requested in such purchase order may not deviate from the amount previously forecasted for such ~~[month]~~ in the most recent prior forecast by more than ~~[fifteen percent (15%)]~~, unless Aerogen otherwise agrees. The quantities forecasted for ~~[the first ninety (90) days]~~ of each forecast shall not deviate from the quantities forecasted for the same ~~[ninety-day]~~ period in the prior forecast by more than ~~[twenty-five percent (25%)]~~, unless Aerogen otherwise agrees. MIA shall place each purchase order for quantities of the OnQ Aerosol Generator at least ~~[thirty (30) days]~~ prior to the delivery date specified therein, and each such purchase order shall be binding on MIA upon receipt by Aerogen. MIA may use its standard purchase order form to order OnQ Aerosol Generators; *provided, however*, that all purchase orders and confirmation memoranda exchanged in connection with an order and delivery of the Product shall be subject to the terms of this Agreement, and any conflicting or additional terms are hereby expressly rejected. Aerogen shall use reasonable efforts to deliver the OnQ Aerosol Generators ordered by MIA under such binding purchase orders by the delivery dates specified in such orders.

4.3 Order Limits. Aerogen shall not be obligated to supply in a calendar month a quantity of OnQ Aerosol Generators that is more than ~~[one hundred fifteen percent (115%)]~~ of the amount previously forecasted for such ~~[month]~~ in the prior forecast submitted by MIA (each, an "Order Limit"). However, if requested by MIA, Aerogen will use reasonable efforts to

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supply any amounts of OnQ Aerosol Generators in excess of the Order Limit for a particular [month]. Aerogen shall notify MIA in writing promptly after receiving a purchase order from MIA whether it is able to supply the amount of such purchase order that exceeds such Order Limit. Any excess amounts that Aerogen accepts (in whole or in part) pursuant to this **Section 4.3** within ten (10) business days after the date of such purchase order shall be binding upon MIA. If Aerogen fails to respond within ten (10) business days after the date of a purchase order that requests delivery of amounts in excess of the Order Limit, then Aerogen shall be deemed to have accepted only the amount of such purchase order that falls within the Order Limit.

4.4 Delivery. Each shipment of OnQ Aerosol Generators will be delivered FCA (Incoterms 2000) the OnQ Aerosol Generator Manufacturing Facility in accordance with the instructions in MIA's purchase orders. Upon MIA's written instructions, and at MIA's risk and expense, Aerogen shall arrange for shipment of OnQ Aerosol Generators to MIA's Product manufacturing location(s). MIA shall maintain a direct-billed account with the common carrier(s) of its choice, and shall inform Aerogen in a timely manner as to which such carrier(s) Aerogen shall use for all OnQ Aerosol Generator shipments.

4.5 Inspection; Defective OnQ Aerosol Generators.

(a) **Inspection; Rejection; Acceptance.** MIA will visually inspect all deliveries of the OnQ Aerosol Generators on arrival. Within ten (10) days of receipt of shipment of OnQ Aerosol Generators, MIA shall promptly give notice to Aerogen of any complaint regarding qualitative and/or quantitative defects of the delivered OnQ Aerosol Generators that are or would have been discovered by a reasonable visual inspection and of its rejection of such OnQ Aerosol Generators. If MIA fails to notify Aerogen of any such defects within such period, MIA shall be deemed to have accepted the OnQ Aerosol Generators. Rejected goods shall be returned freight prepaid to Aerogen within ten (10) days of rejection.

(b) **Sole Remedies.** With respect to any such OnQ Aerosol Generators that Aerogen reasonably determines, pursuant to its failure investigation process, in which MIA may participate at its reasonable request, to have been defective at the time of delivery to MIA pursuant to **Section 4.5(a)**, Aerogen shall, at its option, either repair or replace the defective OnQ Aerosol Generators free of charge, or credit the MIA with the purchase price of the defective OnQ Aerosol Generators. Any replacement goods shall be shipped by Aerogen to MIA freight prepaid. The remedies set forth in this **Section 4.5(b)** are MIA's sole and exclusive remedies for claims based on defective OnQ Aerosol Generators supplied by Aerogen prior to incorporation into assembled Product by MIA, subject to the limited warranty set forth in **Section 9.4** below and the applicable remedies set forth in **Section 9.5**.

4.6 Inventory. In order to prevent out-of-stock situations, at any time during the Term upon Aerogen's request, MIA shall keep an inventory of OnQ Aerosol Generators for assembly into Product in amounts to cover at least MIA's forecasted requirements for the following calendar month. Aerogen will time its production of OnQ Aerosol Generators so as to

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maintain in stock not less than the number of OnQ Aerosol Generators firm-ordered by MIA for delivery within the next thirty (30) days.

5. PAYMENTS.

5.1 Up Front Payments.

(a) In consideration of the Product distribution rights granted by Aerogen to MIA pursuant to **Section 2.1** and the exclusive Product manufacturing and assembly license granted by Aerogen to MIA pursuant to **Section 3.1**, MIA will pay to Aerogen one million five hundred thousand U.S. dollars (\$1,500,000), payable in one installment of five hundred thousand U.S. dollars (\$500,000) to be paid within two (2) business days of the Effective Date, a second installment of three hundred thousand U.S. dollars (\$300,000) to be paid within nine (9) business days of the Effective Date, and a third installment of seven hundred thousand U.S. dollars (\$700,000) to be paid within fifteen (15) business days of the Effective Date.

(b) In consideration of the sale by Aerogen to MIA of the Equipment, MIA will pay to Aerogen within fifteen (15) business days of the Effective Date one million U.S. dollars (\$1,000,000).

5.2 Sub-Distributor Agreement Revenue. MIA shall pay to Aerogen [~~fifty percent~~ (50%)] of any upfront fees, milestone payments and any other payments or consideration obtained by MIA pursuant to the terms of any sub-distributor agreement entered into by MIA as permitted by this Agreement, *but excluding* amounts paid by such sub-distributor, as long as MIA has no financial interest in such sub-distributor, as transfer price for purchase of the Product from MIA, on which amounts Aerogen is paid royalties as specified in **Section 5.3**.

5.3 Sales-Based Payments. In consideration of the rights granted by Aerogen to MIA under this Agreement, MIA will make payments to Aerogen based on the Gross Selling Price of each unit of Product, including Product components and Product accessories, sold by MIA (or its Affiliate or Related Sub-Distributor, as applicable) to sub-distributors or to end-user customers in the Territory. Such payments shall be as set forth in *Exhibit G*. Commencing with the first commercial sale of the Product in the Territory, sales based payments payable to Aerogen under this **Section 5.3** shall be paid on a Sales Quarterly basis during each Sales Year of the Term, within thirty (30) days following the end of each such Sales Quarter.

5.4 Transfer Pricing.

(a) The transfer price for the first thirty thousand (30,000) OnQ Aerosol Generators to be supplied by Aerogen to MIA pursuant to this Agreement will be equal to [~~thirty five U.S. dollars (\$35)~~] per unit. The transfer price for the next fifty two thousand five hundred (52,500) OnQ Aerosol Generators to be supplied by Aerogen to MIA pursuant to this Agreement will be equal to [~~twenty U.S. dollars (\$20)~~] per unit. Aerogen will use reasonable efforts to supply to MIA the first [~~ten thousand (10,000)~~] OnQ Aerosol Generators no later than fifty (50) calendar days following the Effective Date, and [~~twenty thousand (20,000)~~] additional OnQ

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Aerosol Generators no later than one hundred and ten (110) calendar days following the Effective Date.

(b) During the six (6) months immediately following the later of (i) the delivery of the first eighty two thousand five hundred (82,500) OnQ Aerosol Generators or (ii) the Approval Date, up to sixty seven thousand five hundred (67,500) additional OnQ Aerosol Generators will be provided to MIA at [no charge other than shipping, which shall be paid for directly by MIA via an account with a common carrier, and similar out-of-pocket costs,] for which Aerogen will invoice MIA, such invoice to be paid within thirty (30) days of receipt. Such quantity of sixty seven thousand five hundred (67,500) OnQ Aerosol Generators excludes any OnQ Aerosol Generators used in Product provided to Aerogen pursuant to **Section 5.4(e)**.

(c) After the earlier of: (i) the end of such six-month period (provided that Aerogen has satisfied MIA's requirements for quantities of OnQ Aerosol Generators set forth in the forecasts and purchase orders submitted by MIA in accordance with **Sections 4.1 and 4.2**); or (ii) the shipment by Aerogen to MIA of a total of one hundred fifty thousand (150,000) OnQ Aerosol Generators, the transfer price for OnQ Aerosol Generators from Aerogen to MIA will be equal to [twenty U.S. dollars (\$20)] per unit, subject to subclause (d) below and the other provisions of the Agreement, and exclusive of taxes, shipping and similar items.

(d) Aerogen's transfer price to MIA for the OnQ Aerosol Generator may be increased by Aerogen, no more frequently than once in any twelve (12) month period, in an amount not to exceed [the increase in the Producers' Price Index since the date of the last increase], the first such increase to be effective on the earlier of: (i) shipment by Aerogen of a total of [two hundred fifty thousand (250,000)] OnQ Aerosol Generators; or (ii) the second (2nd) anniversary of the Agreement. Notwithstanding the foregoing, Aerogen may adjust the transfer price of OnQ Aerosol Generators to reflect increases in the costs (if any) of unique or scarce materials used in the manufacture of OnQ Aerosol Generators or changes in regulatory requirements that create an increase in OnQ Aerosol Generator manufacturing costs. The Parties will negotiate in good faith the transfer prices for any Product Improvements created during the Term as provided in this Agreement.

(e) Subject to the quantity limits set forth in the forecast to be provided by Aerogen within sixty (60) days after the Effective Date and the minimum order quantity of [150 units] per order, MIA will supply Product to Aerogen at MIA's Cost of Goods [(excluding the cost, if any, of the OnQ Aerosol Generator), plus twenty percent (20%)], to be used by Aerogen to satisfy its Aeroneb® Portable Nebulizer System warranty replacement obligations and distributor and pharmaceutical partner/customer requirements. MIA will receive a credit under **Section 5.4(c)** for its cost of each OnQ Aerosol Generator assembled into Product that is delivered by MIA to Aerogen under this **Section 5.4(e)**. If so requested by Aerogen, MIA also agrees to negotiate in good faith a supply agreement on commercially reasonable terms under which MIA would supply to Aerogen additional Product for use by Aerogen in its business (i.e., outside of the rights granted to MIA under this Agreement).

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5.5 Payment Terms; Reports. For the first [ten thousand (10,000)] OnQ Aerosol Generators delivered by Aerogen to MIA pursuant to this Agreement, MIA shall pay Aerogen the purchase price for OnQ Aerosol Generators as stated on Aerogen's invoice for each shipment via wire transfer initiated within five business (5) days of receipt of each shipment. For the next [seventy two thousand five hundred (72,500)] OnQ Aerosol Generators delivered by Aerogen to MIA pursuant to this Agreement, MIA shall pay Aerogen the purchase price for OnQ Aerosol Generators as stated on Aerogen's invoice for each shipment via wire transfer initiated within five business (5) days of the later of: (a) receipt of written notice from Aerogen confirming that 510(k) marketing clearance has been obtained for the Product; or (b) receipt of each shipment. Thereafter, MIA shall pay Aerogen the purchase price for OnQ Aerosol Generators as stated on Aerogen's invoice for each shipment within thirty (30) days from the date of the invoice. In addition, commencing with the first commercial sale of Product, within thirty (30) days of the end of each Sales Quarter, MIA will provide Aerogen with written sales report listing all Product and components sold, by part number, by country, by country and by sub-distributor and channel of sale, and providing the gross selling price for each such Product, and calculating the royalties owed pursuant to **Section 5.3**. Any payments to Aerogen under this Agreement shall be made by wire transfer to such bank or account as Aerogen shall specify from time to time.

5.6 Late Payments. Any amounts not paid by MIA when due under this Agreement shall be subject to interest from the date payment is due through the date upon which Aerogen has collected immediately available funds in an account designated by Aerogen at a rate equal to the sum of [two percent (2%) plus the prime rate of interest quoted in the Money Rates section of the on-line edition of The Wall Street Journal (at <http://www.interactive.wsj.com>), or other similar reputable data source as agreed by the Parties, calculated daily on the basis of a 360-day year,] or, if lower, the highest rate permitted under applicable law. In the event that MIA fails to make payments for an invoice relating to any of the first [eighty two thousand five hundred (82,500)] OnQ Aerosol Generators when due as specified in **Section 5.5**, such failure shall constitute a material breach of the Agreement, and MIA shall have five (5) business days from the date of written notice by Aerogen to cure such breach by payment via wire transfer to Aerogen of an amount equal to the invoice amount due plus [ten percent (10%)].

5.7 Records and Audit. MIA shall keep, and shall require all its Affiliates and Related Sub-Distributors to keep, complete and accurate records pertaining to the manufacture, sale or other disposition of the Product and components sold and of the amounts payable under this Agreement in sufficient detail to allow the determination of the payments due to Aerogen, or payments owed by Aerogen under **Section 5.4(e)**. Aerogen shall have the right to cause an independent, certified public accountant designated by Aerogen and reasonably acceptable to MIA to audit such records to confirm the accuracy of MIA's payments due hereunder or amounts owed by Aerogen. Such audit rights may be exercised no more often than once a year, within three (3) years after the Sales Quarter to which such records relate, upon reasonable notice to MIA and during normal business hours. Aerogen will bear the full cost of such audit unless such audit discloses an underpayment by MIA, or overpayment by Aerogen, as applicable, of more than five percent (5%) from the amount of payments due, in which case MIA shall bear the full cost of such audit. Within thirty (30) days of the completion of such audit, MIA shall pay to

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Aerogen the amount of any such payment discrepancy disclosed in such audit, or Aerogen shall pay to MIA the amount of any overpayment disclosed in such audit, as applicable. The terms of this **Section 5.7** shall survive any termination or expiration or termination of this Agreement for a period of three (3) years.

5.8 Taxes and Duties.

(a) MIA shall pay all import duties, any and all sales, use, excise, value added, transfer, export or other taxes or assessments, imposed by any governmental authority on any sale to MIA under this Agreement or any of MIA's or its sub-distributors activities, except for any taxes which are imposed on Aerogen's net income, gross receipts or other similar direct taxable income of Aerogen.

(b) If MIA is required to withhold any taxes on amounts payable to Aerogen pursuant to the laws and regulations of a jurisdiction within the Territory, MIA shall deduct withholding taxes from the amounts otherwise payable by MIA hereunder for payment to the proper tax authorities on behalf of Aerogen. MIA agrees to cooperate with Aerogen in the event Aerogen claims exemption from such withholding or seeks deductions under any double taxation or other similar treaty or agreement from time to time in force, such cooperation to consist of providing receipts of payment of such withheld tax or other documents reasonably available to Aerogen.

6. MINIMUMS.

6.1 Minimum OnQ Aerosol Generator Purchases. Commencing on the Effective Date, MIA shall purchase during the Term, on a Supply Quarterly basis, those quantities of OnQ Aerosol Generators set forth in *Exhibit H* for assembly into Systems (as described on *Exhibit B*) of the Product. Such quantities are in addition to the first [one hundred fifty thousand (150,000)] units to be provided pursuant to **Section 5.4** above. Failure by MIA to purchase the minimum quantities during a particular Supply Quarter as set forth in *Exhibit H* shall be deemed to be a material breach for which Aerogen may terminate the Agreement pursuant to **Section 13.5**, unless MIA has purchased, during the calendar year in which such Supply Quarter occurs, more than the aggregate minimum quantities required under *Exhibit H* for such calendar year through such Supply Quarter, and subject further to MIA's right to cure in accordance with **Section 6.2** below, unless such failure is due to supply shortages of the OnQ Aerosol Generators (provided that MIA's orders conform to the terms of **Section 4.2**).

6.2 Minimum Purchase Shortfalls. If MIA has not met its minimum Supply Quarterly purchase requirements (as described on *Exhibit H* and *Exhibit F*), and Aerogen intends to terminate the Agreement pursuant to **Section 13.5**, Aerogen will provide ninety (90) days prior written notice to MIA of its intent to terminate the Agreement for MIA's failure to meet minimum purchasing requirements. Upon notice of intended termination, MIA shall have the right to cure such shortfall in MIA's minimum purchase requirement by purchasing during such ninety-day notice period the amount of such OnQ Aerosol Generators equal to such shortfall plus also purchasing at least MIA's minimum purchase requirements for the Supply Quarter(s) in

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which the ninety-day cure period falls (linearly prorated for the fraction of the second Supply Quarter, if any, in which a portion of the ninety-day-notice period may fall). If MIA purchases such quantities of OnQ Aerosol Generators to cure the minimum purchase shortfall during the ninety-day notice period, and also purchases its prorated minimum purchase requirements for the Supply Quarter(s) in which said cure period falls, Aerogen's notice of termination shall not become effective and the Agreement will continue in full force and effect. Aerogen shall provide to MIA the ninety (90) day notice of termination described in this **Section 6.2**, no later than one hundred twenty (120) days after the end of the Supply Quarter in which such minimum purchase shortfall failure occurs, after which Aerogen's option to terminate for said breach based upon MIA's failure to meet its minimum purchasing requirements for the applicable Supply Quarter will lapse.

6.3 Minimum Royalties. Commencing with the third (3rd) Sales Quarter of the first Sales Year, and on a Sales Quarterly basis thereafter, MIA shall pay to Aerogen, on a country-by-country basis, minimum quarterly royalties which shall be calculated as set forth on **Exhibit I**. Minimum royalties due for each Sales Quarter shall be payable within thirty (30) days following the end of such quarter and shall be credited against sales-based royalty payments due and payable to Aerogen pursuant to **Section 5.3** above. Such minimum royalties will be due and payable with respect to any country that is part of the Territory for any portion of a Sales Quarter, regardless of whether that country remains a part of the Territory thereafter. Notwithstanding this **Section 6.3**, if Aerogen fails, for a period of greater than sixty (60) days, to supply OnQ Aerosol Generators in fulfillment of MIA's purchase orders submitted in accordance with **Section 4.2**, and such supply failure results in Product System backorders for the United States, then during the Sales Quarter(s) in which such OnQ Aerosol Generator supply shortage occurs, MIA shall only be required to pay the actual sales-based royalty payments due and payable to Aerogen pursuant to **Section 5.3** above for Product sales in the United States in such Sales Quarter(s). The minimum royalty requirement for the United States shall be reinstated in the first full Sales Quarter following resolution of the OnQ Aerosol Generator supply shortage.

6.4 Minimum Product System Sales Requirements. Notwithstanding MIA's satisfaction of its OnQ Aerosol Generator purchase requirements as described in **Sections 6.1** and **6.2** above, MIA shall also be required to sell Product Systems (as Systems are defined on **Exhibit A**) in the Sales Quarterly quantities specified for each country on **Exhibit J**. Failure by MIA to sell the minimum quantities as set forth in **Exhibit J** for a particular country in any particular Sales Quarter shall be deemed to be a material breach for which Aerogen may terminate the Agreement with respect to such country pursuant to **Section 13.5**, or the Agreement in its entirety if such country is the United States, in each case unless MIA has sold, during the Sales Year in which such Sales Quarter occurs, more than the aggregate minimum required sales of Product Systems in such country for such Sales Year through such Sales Quarter, as specified in **Exhibit J**, but subject to MIA's right to cure in accordance with **Section 6.5(a)** below, and unless such failure is due to Aerogen's failure to supply OnQ Aerosol Generators (ordered by MIA in compliance with **Section 4.2**) for a period exceeding sixty (60) days that results in Product System backorders in such country immediately following such failure by Aerogen. Aerogen may terminate the Agreement with respect to all of Europe (as defined in **Exhibit J**) if

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MIA fails to sell the aggregate minimum quantities, in any particular Sales Quarter, for all of Europe (as determined by aggregating the minimum sales quantities in *Exhibit J* for each country in Europe in such Sales Quarter), unless MIA has sold, during the Sales Year in which such Sales Quarter occurs, more than the aggregate minimum required sales of Product Systems in all of Europe for such Sales Year through such Sales Quarter, as specified in *Exhibit J* and determined as above, and subject to MIA's right to cure in accordance with **Section 6.5(b)** below, and unless such failure is due to Aerogen's failure to supply OnQ Aerosol Generators (ordered by MIA in compliance with **Section 4.2**) for a period exceeding sixty (60) days that results in Product System backorders in Europe immediately following such failure by Aerogen.

6.5 Minimum Sales Shortfalls.

(a) Individual Countries. If MIA has not met its minimum Sales Quarterly sales requirements for a particular country (as described on *Exhibit J*), and Aerogen intends to terminate the Agreement with respect to such country, or, in the case of the United States, the Agreement in its entirety, pursuant to **Section 13.5**, Aerogen will provide ninety (90) days prior written notice to MIA of its intent to terminate the Agreement with respect to such country for MIA's failure to meet minimum sales requirements. Upon notice of intended termination, MIA shall have the right to cure such shortfall in MIA's minimum sales requirement by selling during such ninety-day notice period the amount of such Product Systems equal to such shortfall in the particular country plus also selling at least MIA's minimum sales requirements in the particular country for the Sales Quarter(s) in which the ninety-day cure period falls (linearly prorated for the fraction of the second Sales Quarter, if any, in which a portion of the ninety-day-notice period may fall). If MIA sells such quantities of Product Systems in the particular country to cure the minimum sales shortfall during the ninety-day notice period, and also sells its prorated minimum sales requirements in the particular country for the Sales Quarter(s) in which said cure period falls, Aerogen's notice of termination shall not become effective and the Agreement will continue in full force and effect with respect to the country.

(b) Europe. If MIA has not met its aggregate minimum Sales Quarterly sales requirement for all of Europe (as indicated in *Exhibit J*) by aggregating the minimum sales quantities for each country in Europe in such Sales Quarter, and Aerogen intends to terminate the Agreement with respect to Europe pursuant to **Section 13.5**, Aerogen will provide ninety (90) days prior written notice to MIA of its intent to terminate the Agreement with respect to Europe for MIA's failure to meet the aggregate minimum sales requirements. Upon notice of intended termination, MIA shall have the right to cure such shortfall in MIA's minimum sales requirement by selling during such ninety-day notice period that quantity of Product Systems equal to such shortfall in Europe plus also selling at least MIA's minimum sales requirements in Europe for the Sales Quarter(s) in which the ninety-day cure period falls (linearly prorated for the fraction of the second Sales Quarter, if any, in which a portion of the ninety-day-notice period may fall). If MIA sells such quantities of Product Systems in Europe to cure the minimum sales shortfall during the ninety-day notice period, and also sells its prorated minimum sales requirements in Europe for the Sales Quarter(s) in which said cure period falls, Aerogen's notice of termination shall not become effective and the Agreement will continue in full force and effect with respect to the country. Such sales may occur in any country then currently within MIA's Europe territory (as

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indicated in *Exhibit J*, as may be amended by the Parties from time to time); *provided, however*, that individual countries within Europe may nevertheless be lost if shortfalls in such countries are not cured as provided in **Section 6.5(a)** above.

(c) **Notice Requirement.** Aerogen shall provide to MIA the ninety (90) day notice of termination described in this **Section 6.5** with respect to a particular country, Europe or the Agreement in its entirety (for a Sales Quarterly minimum sales short fall in the United States), as the case may be, no later than one hundred twenty (120) days after MIA provides to Aerogen pursuant to **Section 5.5** all required reports for the Sales Quarter in which said failure occurs in said area, after which Aerogen's option to terminate for said breach based upon MIA's failure to meet its minimum Sales Quarterly Product System sales in said area for the applicable Sales Quarter will lapse.

6.6 Adjustments to Minimum Purchase, Minimum Royalties and Product System Sales Requirements.

(a) **Europe, Expansion Country Minimum Purchases.** If Aerogen terminates the Agreement with respect to any country in Europe (as described in *Exhibit J*) due to MIA's failure to cure its Sales Quarterly minimum Product System sales shortfalls in such country, MIA's future minimum Supply Quarterly OnQ Aerosol Generator purchases (as described in *Exhibit H*) shall remain firm commitments; *however*, if termination occurs (either by Aerogen as provided above or by MIA as provided in **Section 13.3**) with respect to any other country in the Territory (other than the United States), or for Europe in its entirety, MIA's future minimum Supply Quarterly OnQ Aerosol Generator purchases will be adjusted to reflect such termination.

(b) **Europe, Expansion Country Royalty, Sales Reductions.** Any termination of the Agreement with respect to a particular country or Europe in its entirety will result in a commensurate reduction of the minimum royalties (*Exhibit I*) and Product System sales requirements (*Exhibit J*) attributable to such country or Europe, effective in the first Sales Quarter in which such country or Europe is no longer part of the Territory.

(c) **U.S. Minimums Adjustments.** The minimum Supply Quarterly OnQ Aerosol Generator purchase quantities and minimum Sales Quarterly Product Systems sales requirements for the United States, as described in *Exhibit H* and *Exhibit J*, respectively, for Sales Quarters nine (Q9) through twenty (Q20) shall be discussed by the Parties in Sales Quarter seven (Q7) of the Term, and, if mutually agreed upon, adjusted to no less than [seventy five percent (75%)] of the stated minimum for said quarters as of the Effective Date.

7. REGULATORY AND CUSTOMER SUPPORT MATTERS.

7.1 Regulatory Filings. Aerogen will be solely responsible for obtaining FDA 510(k) marketing clearance for the Product and marketing clearance in the European Union, at no expense to MIA. For all other countries in the Territory, MIA shall be responsible for preparing a reasonably detailed plan and practical schedule for obtaining all necessary marketing clearances for each such country within sixty (60) days following the Effective Date. Aerogen, and/or its

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authorized agent(s), will be responsible for obtaining marketing clearance from the appropriate Regulatory Agency at MIA's expense, provided that, for clarity, MIA shall have no responsibility for any expenses associated with Aerogen's ISO compliance. MIA shall provide all regulatory and technical information relating to its manufacture of the Product as reasonably requested by Aerogen, and shall otherwise assist Aerogen in obtaining any necessary or desirable regulatory approvals in the Territory. Aerogen will promptly advise MIA each time that it obtains marketing clearance for the Product in a country or jurisdiction in the Territory. Aerogen shall grant to MIA a right of reference to the marketing clearances obtained by Aerogen in the Territory.

7.2 Medical Device and Vigilance Reporting. MIA shall be responsible for receiving, investigating, and documenting all complaints which may, or may not, be Medical Device Reportable ("MDR") events and other adverse experiences relating to the use of the Product sold or distributed by MIA or its Affiliates or sub-distributors. MIA will be solely responsible for filing all reports of such events, including, but not limited to, MDR Reports, Vigilance Reports, Reports of Corrections and Removals, recalls and any other reports required by Regulatory Agencies, or as required by applicable laws or regulations. In the event that MIA receives a report of an adverse experience relating to the use of the Product anywhere in the world, it shall notify Aerogen in writing within five (5) business days, or if such event is serious and unexpected, within forty eight (48) hours.

7.3 Customer Support. MIA shall have sole responsibility for providing first-line Product support to sub-distributors and customers, and for responding to questions and complaints relating to Product from its sub-distributors and customers, all at MIA's expense. Complaints received by MIA from sub-distributors or customers, which MIA determines to be related to the OnQ Aerosol Generator, shall be promptly referred to Aerogen. MIA shall cooperate as reasonably required to allow Aerogen to determine the cause of and resolve any complaints regarding the OnQ Aerosol Generator. Any such complaints that are determined by Aerogen to relate solely to OnQ Aerosol Generator performance shall be investigated and resolved at Aerogen's expense. MIA will provide Aerogen with monthly reports of complaints received, and actions taken. MIA will be responsible for coordinating and handling product returns and replacements relating to customer complaints, and shall bear the costs thereof. Aerogen will provide administration/support for MIA's customer support activities, if requested by MIA, at an agreed upon rate of reimbursement to Aerogen. MIA shall be responsible for complying with all applicable regulations and laws as they relate to complaint handling and closure.

7.4 Recall. If either Party believes or is notified that a recall in the Territory of the Product is desirable or required by law, it will promptly notify the other Party. The Parties will then discuss reasonably and in good faith whether such recall is appropriate or required and the manner in which any mutually agreed recall shall be handled. In the event of a recall, the Parties shall bear the expenses incurred in connection with such recall ratably and in proportion to their, or their agents' and/or Affiliates', relative responsibility for the cause of such recall.

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7.5 Inspections. MIA shall notify Aerogen promptly of any inspection or regulatory actions by representatives of any governmental agency within the Territory concerning the Product and shall provide Aerogen with copies of all correspondence relating to the inspection and/or action, including, but not limited to, any Form 483s, Establishment Inspection Reports, FDA Warning Letters, and/or Untitled Letters. MIA shall also provide Aerogen with a summary of the results of such inspection and such actions, if any, taken to remedy conditions cited in such inspections. Both Parties agree to cooperate fully with each other in connection with any inquiry or inspection conducted by a governmental agency concerning the Product.

8. PRODUCT BRANDING; MARKETING MATERIALS; TRADEMARKS.

8.1 Co-Branding. MIA agrees that it will brand the Product distributed by it (and its Affiliates and sub-distributors) in the Territory using both MIA and Aerogen brands and trademarks (including the Trademarks) as jointly agreed by the Parties, and in conformance with the agreed upon branding strategy for each country in the Territory.

8.2 Annual Business Plan and Review. During the Term, Representatives from MIA and Aerogen shall meet annually, no later than October 31 of each year, to present and discuss MIA's detailed marketing plans and budgets for the following calendar year in each of the countries in the Territory. To the extent that MIA markets the Product entirely via sub-distributors in a country, MIA shall present said sub-distributors plans in comparable detail to MIA's own plans.

8.3 Product Marketing Materials. Aerogen will make available to MIA any marketing materials for the Product that have been prepared by Aerogen as of the Effective Date, including Aerogen's Product branding and messaging, brand standards, retail packaging design, and pre-launch marketing materials. During the Term, Aerogen shall provide such additional marketing support as reasonably requested by MIA, at MIA's expense. MIA will provide to Aerogen copies of all promotional literature, sales aids, technical information, and clinical publications intended to be used by MIA in connection with promotion or distribution of the Product for review and final approval by Aerogen. Each Party will provide the other with reports available to it of any clinical studies and in vitro data for the Product that may be performed by or on behalf of such Party, and Aerogen will provide reasonable technical support and technical troubleshooting expertise as it relates to the OnQ Aerosol Generator, and Product design. In the event that MIA requires Aerogen's assistance with issues relating to Product manufacture, such assistance will be provided by Aerogen on an as-available basis, and at MIA's expense. MIA will be obligated to provide to Aerogen no more than [one hundred (100)] Product Systems per year, [at no cost to Aerogen], for use in Aerogen's marketing, research activities, and other purposes.

8.4 Trademark License. Subject to the terms of this Agreement, Aerogen hereby grants to MIA during the Term a non-exclusive, nontransferable, royalty-free license (with no right to sublicense) to use the Trademarks in each country of the Territory in connection with the marketing, sale and distribution of Product in the Territory as permitted under Sections 2.1 and 3.1.

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8.5 Trademark Use. MIA will display the Trademarks designated by Aerogen for the OnQ Aerosol Generator on each Product component that bears a Trademark, and on all packaging and labeling. Any use of the Trademarks by MIA shall be in conformity with Aerogen's trademark usage guidelines and other instructions. MIA may use its own trademarks and trade names on Product labeling and packaging for the purpose of identifying MIA as manufacturer and distributor of the Product in the Territory to the extent permitted by law; *provided, however*, that in no event shall MIA's trademarks or trade names appear more prominent than Aerogen's Trademarks. Aerogen grants no rights other than those expressly granted hereunder, and MIA hereby agrees to and recognizes Aerogen's exclusive ownership of the Trademarks. MIA agrees not to take any action inconsistent with such ownership and further agrees to take any action, at Aerogen's expense, which Aerogen reasonably deems necessary to establish and preserve Aerogen's exclusive rights in and to the Trademarks including but not limited to cooperating in the registration of the Trademarks on trademark registries or other appropriate registration procedure in the Territory. If MIA, in the course of distributing Product, acquires any goodwill or reputation in the Trademarks, then at the expiration or termination of this Agreement all such goodwill and reputation automatically shall vest in Aerogen without any separate payment or consideration of any kind to MIA, and MIA agrees to take all actions necessary to effect such vesting.

8.6 No Similar Marks. MIA shall not adopt, use, or register any acronym, trademark, trade names, service mark or other marketing name that is confusingly similar to the Trademarks or the Aerogen name, other than in connection with distribution of Product pursuant to this Agreement, and shall not use the Trademarks or the Aerogen name other than in connection with distribution of Product pursuant to this Agreement.

9. REPRESENTATIONS AND WARRANTIES; LIMITATION OF LIABILITY.

9.1 Mutual Representations and Warranties. Each Party hereby represents and warrants that:

(a) it is duly organized and validly existing under the laws of the state of its incorporation and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

(b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder;

(c) the person executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action;

(d) this Agreement is a legal and valid obligation binding upon it and enforceable in accordance with its terms, subject to bankruptcy, insolvency or similar laws of general application affecting the enforcement of rights of creditors, and subject to equitable principles limiting rights to specific performance or other equitable remedies, and subject to the

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effect of federal and state securities laws on the enforceability of indemnification provisions relating to liabilities arising under such laws;

(e) the execution, delivery and performance of this Agreement does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body, or administrative or other agency having jurisdiction over it;

(f) it has obtained all necessary consents that are required with respect to the execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereby; and

(g) there is no broker, finder or other intermediary that has been retained by or authorized to act for such Party who would be entitled to any fee or commission upon entry into the Agreement.

9.2 Additional Representations and Warranties of Aerogen. Except as otherwise provided in the disclosure schedule attached as *Schedule 9.2* (the "**Disclosure Schedule**"), Aerogen represents and warrants that as of the Effective Date:

(a) no insolvency proceeding of any kind, whether voluntary or involuntary, is pending, or to Aerogen's knowledge threatened, against Aerogen, and Aerogen has not taken any action to initiate any insolvency proceeding, whether voluntary or involuntary;

(b) Aerogen believes that, based on its existing agreements with its suppliers, it has sufficient access to raw materials of the quality, quantity and condition needed to manufacture the OnQ Aerosol Generator to be supplied under this Agreement;

(c) no unsatisfied judgment is presently pending against Aerogen that relates to the Product or the Equipment, and there are no actions, suits or proceedings before any court, agency or other governmental body pending or, to Aerogen's knowledge, threatened against Aerogen relating to the Product or the Equipment;

(d) since the last public disclosure by Aerogen (the 10-Q filed on August 14, 2003, which contains financial statements as of June 30, 2003), Aerogen has conducted its operations in the normal course consistent with past practices and there has been no material adverse change in Aerogen's business, assets, or liabilities relating to the Product or Equipment;

(e) Aerogen does not have any reason to believe that any loss of an employee, or supplier will result because of the consummation of the transactions contemplated under this Agreement;

(f) Aerogen has not received notice of alleged material violations of any law, statute, order, rule or regulation that relates to the Product or the Equipment;

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(g) Aerogen, with respect to the Equipment, the OnQ Aerosol Generator or the Product, as applicable, is not a party to or subject to: (i) any lease with respect to any portion of the Equipment, whether as lessor or lessee; (ii) any contract for the purchase of materials, supplies, goods, services, or equipment in excess of the requirements of the manufacture of OnQ Aerosol Generators for normal operating procedures; (iii) any agreement, contract, or commitment to sell or supply OnQ Aerosol Generators in excess of [\$250,000]; and (iv) any license agreement, franchise agreement or agreement in respect to similar rights granted to or held by MIA with respect to the Product.

(h) (i) the Equipment constitutes all of the equipment used or held for use by Aerogen primarily for manufacturing OnQ Aerosol Generators; (ii) upon the completion of the transaction contemplated by **Section 3.8(c)**, MIA will have acquired good and marketable title to the Equipment, free and clear of all liens, claims, and encumbrances; (iii) *Exhibit E* contains a correct and complete list of all the Equipment; and (iv) the Equipment is in good operating condition and repair, subject to normal wear and maintenance, and is useable in the ordinary course of manufacturing OnQ Aerosol Generators;

(i) (i) to Aerogen's knowledge, it Controls all rights it purports to grant to MIA to the Aerogen Licensed Rights pursuant to this Agreement; and (ii) it has not received any notice or claim that the Aerogen Licensed Rights infringe upon the intellectual property rights of a third party;

(j) to Aerogen's knowledge, it is in material compliance with all laws, rules and regulations relating to the environment with respect to the Equipment and the OnQ Aerosol Generator Manufacturing Facility at its location as of the Effective Date;

(k) to Aerogen's knowledge, no schedule, certificate, document or written statement furnished to MIA by or on behalf of Aerogen in connection with this Agreement contains any untrue statement of a material fact or omits to state a material fact necessary to make such statements not materially misleading; and

(l) Aerogen has taken all reasonable actions legally appropriate, including requiring the execution of confidentiality agreements, to protect Aerogen's Confidential Information and the confidential portions of the Aerogen Technology from disclosure to unauthorized third parties by any of its personnel, agents, subcontractors or vendors who have had significant involvement with the design, engineering, manufacturing, sales, or marketing of the Product; and

(m) Aerogen will perform the OnQ Aerosol Generator manufacturing services to be provided pursuant to **Section 3.8(d)** during the OnQ Manufacturing Period in accordance with generally accepted professional design, engineering, and manufacturing standards in effect at the time of such performance.

9.3 Additional Representations and Warranties of MIA. MIA represents and warrants to Aerogen that:

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(a) it has, or will acquire, and will maintain during the Term all government permits and licenses including, without limitation, health, safety, and environmental permits, necessary for MIA's Product manufacturing, distribution and sales activities contemplated by this Agreement;

(b) a Product manufactured by MIA in the exercise of its rights under this Agreement will be manufactured in accordance with the Product Specifications; and

(c) as of the Effective Date, Neither MIA nor its Affiliates have an existing or in-negotiation financial interest (including, but not limited to, equity ownership, credit facilities, or other economic rights) in any sub-distributor in the Territory; and (ii) no sub-distributor in the Territory has an existing or in-negotiation financial interest in MIA.

9.4 Limited Warranty. Aerogen warrants to MIA that each OnQ Aerosol Generator supplied under this Agreement, shall at the time of shipment and for a period of seventeen (17) months thereafter, conform in all material respects to the OnQ Aerosol Generator Specifications listed on *Exhibit A*.

9.5 Exclusive Remedies. Aerogen will, at its option, repair, replace or otherwise correct any OnQ Aerosol Generator that does not conform to the warranty set forth in **Section 9.4** above, *provided* that:

(a) For OnQ Aerosol Generators that have not been incorporated into Product that has been sold by MIA, MIA has notified Aerogen of such nonconformity pursuant to **Section 4.5(a)**, with respect to apparent defects, within ten (10) days after Aerogen's delivery of a nonconforming OnQ Aerosol Generator; and, with respect to hidden defects which could not reasonably be discovered within such ten (10) day visual inspection period, before the expiration of three (3) months from Aerogen's delivery of the nonconforming OnQ Aerosol Generator;

(b) For OnQ Aerosol Generators that have been incorporated into Product that has been sold to an end-customer by MIA or MIA's sub-distributors, MIA has notified Aerogen of such nonconformity within fifteen (15) months from Aerogen's delivery of the nonconforming OnQ Aerosol Generator;

(c) MIA, at Aerogen's request and MIA's expense, returns the nonconforming OnQ Aerosol Generator to Aerogen's facility; and

(d) such nonconformity is not the result of any mishandling, abuse, damage, or use of the OnQ Aerosol Generator other than in strict accordance with Aerogen's instructions.

9.6 Disclaimer. EXCEPT AS SET FORTH IN **SECTION 9.4** ABOVE, THE ONQ AEROSOL GENERATORS ARE DELIVERED TO MIA "AS IS" AND AEROGEN MAKES NO WARRANTIES WITH RESPECT TO THE ONQ AEROSOL GENERATORS, EXPRESS OR IMPLIED, AND SPECIFICALLY, WITHOUT LIMITATION, DISCLAIMS ANY IMPLIED WARRANTY OR MERCHANTABILITY, WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR WARRANTY OF NON-INFRINGEMENT OF THIRD PARTY INTELLECTUAL

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PROPERTY RIGHTS. The warranties shall apply only if the final analysis and report from Aerogen's failure investigation process, in which MIA may participate at its reasonable request, with a copy of such report to be provided to MIA upon its reasonable request, discloses that alleged defects actually exist and were not caused by misuse, unauthorized modifications, neglect, improper use or storage, attempts to repair, or the like, or by accident, fire, or other hazard.

9.7 No Warranty Pass-Through. MIA shall not pass through to customers or any other third party the warranties made by Aerogen under this **Article 9**, shall make no representations to sub-distributors or customers other than that they must look solely to MIA in connection with any problems, warranty, claim or other matters concerning the Product. No warranty, representation or agreement herein shall be deemed to be made for the benefit of any sub-distributor or customer of MIA or any other third party.

9.8 Limitation of Liability. IN NO EVENT SHALL AEROGEN BE LIABLE FOR ANY INDIRECT, INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES, INCLUDING LOSS OF PROFITS, REVENUE, OR USE, INCURRED BY MIA OR ANY THIRD PARTY, WHETHER IN AN ACTION IN CONTRACT OR TORT OR BASED ON A WARRANTY, EVEN IF AEROGEN HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. EXCLUDING AEROGEN'S INDEMNIFICATION OBLIGATION SET FORTH IN **SECTION 11.1** BELOW, AEROGEN'S LIABILITY FOR ANY DAMAGES UNDER THIS AGREEMENT SHALL IN NO EVENT EXCEED THE AMOUNTS ACTUALLY PAID BY MIA TO AEROGEN UNDER THIS AGREEMENT.

10. INTELLECTUAL PROPERTY.

10.1 Ownership of Intellectual Property Rights. Aerogen shall retain all of its right, title and interest in and to and ownership of the Product, the OnQ Aerosol Generator and the Aerogen Licensed Rights, subject only to the manufacturing and distribution rights granted to MIA pursuant to this Agreement. Aerogen will own all Product Improvements, Manufacturing Improvements and any other improvements, modifications or enhancements to the Product or the OnQ Aerosol Generator made by either Party (collectively, the "**Developed IP**"). Except as otherwise expressly provided in this Agreement, MIA has no right, title or interest in the Product, the Aerogen Technology or any Aerogen Licensed Rights and shall not reproduce or otherwise use or practice, in whole or in part, the Product, the Aerogen Technology or the Aerogen Licensed Rights except as permitted by this Agreement.

10.2 Cooperation and Assistance. At Aerogen's request, MIA shall execute and deliver to Aerogen all descriptions, applications, assignments and other documents and instruments necessary or proper to perfect and assert ownership of the Developed IP as contemplated by **Section 10.1**. MIA shall cooperate with and assist Aerogen, at Aerogen's expense, in Aerogen's efforts in obtaining, maintaining, defending and enforcing its intellectual property rights in the United States and elsewhere.

10.3 Enforcement of Intellectual Property Rights. MIA agrees that only Aerogen has the right to enjoin any infringement or registration by a third party of the Trademarks or the

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Aerogen Licensed Rights relating to the Product. In the event that any unlawful infringement of Aerogen's rights in the Product, or infringement or registration by a third party of the Trademarks or other intellectual property rights of Aerogen in the Territory comes to the attention of MIA, MIA shall immediately inform Aerogen in writing, stating the full facts of the infringement or registration known to it, including the identity of the suspected infringer or registrant, the place of the asserted infringement or registration and evidence thereof. MIA agrees to cooperate fully with Aerogen, at Aerogen's expense for MIA's reasonable out-of-pocket costs, if Aerogen sues to enjoin such infringements or to oppose or invalidate any such registration.

10.4 Infringement of Third Party Intellectual Property Rights. In the event that the manufacture, use or sale of the Product infringes or misappropriates third party Intellectual Property Rights, Aerogen may, in its sole discretion, (a) obtain for MIA the right to continue to market, sell and distribute the Product in the Territory, (b) replace or modify the Product so as to make the Product non-infringing, or (c) terminate MIA's rights to distribute the Product in the Territory by written notice effective upon receipt pursuant to **Section 14.9**, but subject to **Section 13.6(b)**. Aerogen may, in its sole discretion, enter into a settlement with the third party, including but not limited to, obtaining the rights described in subsection (a) above. If Aerogen terminates pursuant to subsection (c) above, MIA will remove all Product from the market and will cease distributing the Product. Aerogen shall not be obligated to indemnify MIA for third party claims arising out of the Product's infringement of any intellectual property right of a third party resulting from MIA's (x) modification of the Product by MIA other than Product Improvements or Manufacturing Improvements made pursuant to **Section 3.4(a)**, (y) the combination of the Product with other technology or devices or (z) the modification, misuse or mishandling of OnQ Aerosol Generators after delivery thereof pursuant to **Section 4.4**.

11. INDEMNITY.

11.1 Indemnification by Aerogen. Aerogen shall indemnify, defend and hold harmless MIA and its directors, officers, employees and agents from and against any and all third party suits, claims, actions, demands, liabilities, expenses, or losses (including legal expenses and reasonable attorneys' fees) (collectively, "**Claims**") arising out of or resulting from: (a) a defect in the design or manufacture of the OnQ Aerosol Generator; (b) any defect in the design of the Product as of the Effective Date; (c) any negligent actions or willful misconduct by Aerogen; or (d) any infringement of third party Intellectual Property Rights directly resulting from the manufacture, use or sale of the Product up to the date of receipt of notice given pursuant to **Section 10.4**. Such indemnity shall not apply to the extent that MIA has an indemnity obligation for such Claim pursuant to **Section 11.2**. The foregoing indemnity does not apply to any Claim to the extent such Claim is based on manufacturing defects in any portion or component of the Product or Product Improvement not manufactured by Aerogen, or the use, combination or inclusion of any such Product or Product Improvement, component or portion thereof, with any other product.

11.2 Indemnification by MIA. MIA shall indemnify, defend and hold harmless Aerogen and its directors, officers, employees and agents from and against any and all Claims arising out of or resulting from: (a) MIA's failure to adhere to the terms of this Agreement;

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(b) any damage to the OnQ Aerosol Generators occurring after shipment from Aerogen to MIA; (c) the sale or other distribution of Product by MIA or its sub-distributors or use by any customer, (d) any representation made or warranty given by MIA with respect to the Product, (e) the manufacture, sale or use of any product that is not supplied by Aerogen and that is sold or combined with the Product, (f) any negligent actions or willful misconduct by MIA, or (g) any failure by MIA or its agents to comply with all regulatory and/or legal requirements in the Territory, including, but not limited to, promotion of off-label use. Such indemnity shall not apply to the extent that Aerogen has an indemnity obligation for such Claim pursuant to Section 11.1.

11.3 Conditions of Indemnification. If either Party is entitled to indemnification under this Article 11 (the “Indemnified Party”), it shall give prompt written notice to the Party providing indemnification (the “Indemnifying Party”) of any Claims that may be subject to indemnification promptly after learning of such Claim. The Indemnifying Party shall assume, manage and control (by way of intervention or otherwise) the defense and/or settlement of any such Claim. The Indemnified Party will cooperate in the defense or settlement negotiations as reasonably required by the Indemnifying Party. The Indemnifying Party shall not agree to any settlement that may adversely affect the Indemnified Party’s rights or interest without the Indemnified Party’s prior written approval (which approval shall not be unreasonably withheld).

11.4 Insurance. During the Term, each Party shall obtain and maintain at its own cost and expense, comprehensive general liability insurance, including products liability insurance, through reputable and financially secure insurance carriers, adequate to cover its obligations under this Agreement. Such insurance, (a) shall be in an amount which is customarily carried by companies introducing new medical devices, and (b) shall cover claims incurred, discovered, manifested, or made during or after expiration of this Agreement. Each Party agrees to furnish the other Party with a certificate of insurance evidencing the same within thirty (30) days after the Effective Date, and thereafter upon any material change in its coverage described above.

12. CONFIDENTIALITY.

12.1 Disclosure of Confidential Information. During and in furtherance of this Agreement, each Party may disclose certain of its Confidential Information to the other Party. During the term of this Agreement, and for a period of [seven (7) years] after its termination or expiration, each Party agrees (a) to use the other Party’s Confidential Information solely as necessary to perform its obligations or exercise its rights under this Agreement, (b) to hold in strict confidence all Confidential Information of the other Party, and (c) to not disclose the other Party’s Confidential Information to any third party without the prior written consent of the other Party. Notwithstanding the foregoing, each Party may disclose the other Party’s Confidential Information to its directors, officers, employees, contractors and agents as necessary for the purposes contemplated under this Agreement; *provided* that such directors, officers, employees, contractors and agents are bound by obligations of confidentiality and non-use with respect to such Confidential Information that are at least as restrictive as those set forth in this Agreement.

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12.2 Exceptions. The obligations of non-disclosure and non-use set forth in **Section 12.1** shall not apply to any Confidential Information or portion thereof to the extent that the Party receiving such information can demonstrate, by competent proof, that such information (a) was already known by the receiving Party, other than under an obligation of confidentiality, at the time of disclosure, (b) was generally available to the public or otherwise part of the public domain at the time of disclosure, (c) later became part of the public domain through no act or omission of the receiving Party, (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 developed by employees of either Party who were unaware of and did not have access to the Confidential Information.

12.3 Authorized Disclosure. Subject to any applicable legal requirements, each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary in the following: (a) filing or prosecuting patents relating to Product; (b) regulatory filings; (c) prosecuting or defending litigation; (d) complying with applicable governmental regulations; and (e) disclosure to Affiliates, sub-distributors and potential future investors who agree to be bound by similar terms of confidentiality. Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to this **Section 12.3**, it will, except where impracticable, give reasonable advance notice to the other Party of such disclosure and use best efforts to secure confidential treatment of such information. In any event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder.

13. TERM AND TERMINATION.

13.1 Term. The term of this Agreement shall commence as of the Effective Date and continue for a period of five (5) years from the Effective Date, unless terminated earlier as provided in this **Article 13** (the "**Term**"). Unless the Agreement is earlier terminated, the Term shall be extended on the fifth (5th) anniversary of the Effective Date for a period of one (1) year; *provided* that MIA is not then in material breach of the Agreement (subject to the cure periods set forth in **Section 13.5**) and MIA has met the Minimum Purchase Requirements, subject to agreement by the Parties as to appropriate pricing and minimums for such additional time period.

13.2 Termination for Failure to Make Payments. Aerogen shall have an immediate right of termination if MIA fails to make any of the initial payments set forth in **Section 5.1** on the dates specified in **Section 5.1** or fails to honor the initial purchase order provided to Aerogen pursuant to **Section 4.1**. Such termination shall be immediately effective upon the receipt by MIA of written notice of termination for any such failure. On the effective date of such termination, all of the rights and licenses granted by Aerogen to MIA pursuant to this Agreement shall immediately terminate.

13.3 Termination by MIA for Convenience. MIA may terminate this Agreement on a country-by-country basis, except as otherwise provided below, or in its entirety, at any time upon ninety (90) days prior written notice to Aerogen. Notwithstanding the foregoing, any termination by MIA with respect to one or more countries in Europe (as defined in *Exhibit J*)

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period of one year after such termination. In addition, if such termination occurs prior to the date two (2) years after the Effective Date, then (unless the Parties otherwise agree) Aerogen shall reimburse MIA for the payments made to Aerogen by MIA under **Sections 5.1(a)** of the Agreement on a pro-rata basis (determined by multiplying the sum of such payments by a fraction having a numerator equal to the number of months from the date of such termination until the fifth (5th) anniversary of the Effective Date, and a denominator equal to sixty (60) months), plus the sum of any amounts received by Aerogen from MIA pursuant to **Sections 5.1(b)** and **5.4(a)** reduced by twenty U.S. dollars (\$20) per OnQ Aerosol Generator unit supplied by Aerogen to MIA during the Term up to a maximum of one hundred fifty five thousand (155,000) units.

(iii) If Aerogen elects after the one (1) year period set forth in subclause (ii) above to re-introduce the Product for use in the home-based, open-cup, continuous-flow, general nebulizer market or in alternate care facilities, it shall so notify MIA, and MIA shall have a right of first negotiation, exercisable by written notice to Aerogen within thirty (30) days of Aerogen's notice, to obtain the rights to distribute the Product upon terms to be mutually agreed upon by the Parties. If the Parties are unable to reach a definitive agreement regarding such rights after ninety (90) days of good faith negotiations, or if MIA fails to exercise its right of negotiation within the specified thirty (30) day period, Aerogen shall have no further obligation to MIA with respect to distribution rights for the Product for use in the home-based, open-cup, continuous-flow, general nebulizer market or in alternate care facilities.

(iv) If Aerogen elects after the one (1) year period set forth in subclause (ii) above to re-introduce the Product for use in the home-based, open-cup, continuous-flow, general nebulizer market or in alternate care facilities, and MIA subsequently exercises its negotiation right as provided in subclause (iii) above, provided that the termination by Aerogen occurs after the second (2nd) anniversary of the Effective Date, then (1) MIA shall receive a pro-rata credit of the payment made under **Section 5.1(a)** towards the financial terms of the negotiated definitive agreement (*i.e.*, the credit shall equal a percentage amount (such amount, the "**Pro-Rata Amount**") of such payment where the percentage is equivalent to the fraction of (x) the amount of time from the date of such termination until the fifth (5th) anniversary of the Effective Date, to (y) five (5) years), or (2) if the Parties do not enter into such negotiated definitive agreement, and Aerogen subsequently either (A) signs an agreement with a third party for distribution of the Product within the United States or (B) itself sells the Product directly within the United States, then Aerogen shall pay to MIA an amount equal to the Pro-Rata Amount within thirty (30) days of the execution of such third party agreement, or if Aerogen sells the Product directly, Aerogen will pay to MIA, on a quarterly basis, ten percent (10%) of Aerogen's gross sales of Product until the Pro-Rata Amount is paid in full.

(c) General. Upon termination of the Agreement for any reason, MIA's obligation to pay Aerogen sales-based royalties pursuant to **Section 5.3** shall also terminate upon the effective date of such termination; *provided, however*, that unpaid minimum royalties for the Sales Quarter in which termination becomes effective and any unpaid or accrued royalties, which shall be calculated on Product sales made through the effective date of the termination, shall be due and payable to Aerogen within thirty (30) days of such termination effective date. In

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addition, should Product sales continue after the effective date of termination pursuant to **Section 13.7** or by mutual agreement, royalties on such sales, calculated as provided in **Section 5.3**, shall also be payable to Aerogen on a monthly basis, in arrears.

13.7 Transfer or Sell-Out of Inventory. On the effective date of expiration or termination of this Agreement, Aerogen shall have the right to require that MIA cease its manufacturing of the Product, provided that MIA may sell its remaining inventory of Product for a period not to exceed ninety (90) days after such date, for so long as such Product is saleable (unless termination is under **Section 13.4**). Any inventory remaining after such period shall be, at Aerogen's election, (a) sold by MIA or (b) transferred to Aerogen against payment of a purchase price representing MIA's Cost of Goods for the Product and the costs incurred for the shipping of the Product to Aerogen. Notwithstanding the foregoing, if Aerogen terminates this Agreement under **Section 13.4** Aerogen shall have the right to prohibit MIA from selling any remaining inventory, and shall at Aerogen's election, destroy or return to Aerogen all remaining Product, in which case, Aerogen shall reimburse MIA for its cost of OnQ Aerosol Generators assembled into such Product.

13.8 Cooperation and Return of Materials. Upon termination of the Agreement for any reason, including the end of the Term, MIA will cooperate fully with Aerogen to transfer all sales, marketing, manufacture and customer support activities in an orderly fashion to Aerogen or to its designees. Aerogen shall have the right, at its discretion, to obtain from MIA at MIA's documented cost, any tooling, designs for improvements, and other manufacturing-related materials generated by MIA for the manufacture and assembly of Product. On the effective date of termination or no later than ninety (90) days thereafter if MIA elects under **Section 13.7** to sell out its remaining inventory, MIA shall return to Aerogen or its nominee all price lists, catalogs, sales literature, operating and service manuals, advertising literature and other materials relating to the Product. Upon the termination or expiration of this Agreement, each Party shall use diligent efforts (including, without limitation, performing a diligent search of files and computer storage devices) to return all Confidential Information received by it from the other Party within sixty (60) days after the effective date of such termination.

13.9 Survival. Expiration or termination of this Agreement shall not release, or be construed as releasing, any Party from any liability to the other arising out of or in connection with a Party's breach of, or failure to perform any obligation contained in this Agreement. Neither Party shall be relieved from any obligations vested prior to the date of termination of this Agreement. The following provisions shall survive any expiration or termination of this Agreement: Sections 3.6, 5.6, 5.7, 7.3, 7.4, 9.6, 9.8, 10.1, 13.6, 13.7, 13.8, and 13.9 and Articles 1, 11, 12 and 14.

14. MISCELLANEOUS.

14.1 Export Law Compliance. MIA understands and recognizes that the Product and other materials made available to it hereunder may be subject to the export administration regulations of the United States Department of Commerce and other United States government regulations related to the export of medical products. MIA represents that it is familiar with and

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agrees to comply with all such regulations, including any future modifications thereof, in connection with the manufacture and distribution of the Product. MIA agrees that it will not manufacture, sell or distribute the Product or clinical data relating to the Product without complying with all applicable regulations.

14.2 Non-Solicit. Each Party agrees it will not knowingly hire or solicit any of the other Party's employees or sales representatives during the Term and for a period of one (1) year following termination; *provided* that (a) the employee or sales representative was employed or retained by the other Party on the date of termination of the Agreement, and (b) each Party provides the other with a list of employees and sales representatives as of the effective date of termination of the Agreement. This foregoing shall not apply to Aerogen employees directly involved in the manufacture of OnQ Aerosol Generators if Aerogen files for Chapter 7 bankruptcy during the OnQ Manufacturing Period.

14.3 Force Majeure. Neither Party shall be liable to the other for any failure or delay in performance hereunder where such failure or delay is due, in whole or in part, to any cause beyond its reasonable control, including but not limited to acts of God, fire, earthquake, flood, warfare, acts of terrorism, labor disputes, government regulations or other similar events. The Party affected by force majeure shall inform the other Party promptly of the event, an estimate of the period during which performance of its obligations is compromised, and shall undertake all reasonable efforts to overcome the event and resume the performance of its obligations as quickly as possible.

14.4 Severability. In case one or more of the provisions contained in this Agreement shall be invalid, illegal or unenforceable in any respect under any applicable statute or rule of law, then such provision shall be considered inoperable to the extent of such invalidity, illegality or non-enforceability and the remainder of this Agreement shall continue in full force and effect. The Parties hereto agree to replace any such illegal or unenforceable provision with a new provision which has the most nearly similar permissible economic effect.

14.5 Entire Agreement. This Agreement and any exhibits referred to herein state the complete and final agreement of the Parties with respect to the subject matter hereof, and shall supercede all previous communications, understandings and agreements between the Parties with respect to the subject matter of this Agreement, including without limitation, the Letter Agreement regarding confidentiality between the Parties dated February 25, 2003.

14.6 No Third Party Beneficiaries. Except as expressly provided to the contrary, provisions of this Agreement are solely for the benefit of the Parties to this Agreement, and not for the benefit of any other person or legal entity.

14.7 Amendments. No waiver, alteration, amendment, or modification of any of the provisions of this Agreement shall be binding unless made in writing with express reference to this Agreement, and signed by a duly authorized representative of each Party.

14.8 Assignment; Successors. Neither Party may assign any of its rights and obligations hereunder without the prior written consent of the other Party, and any such assignment or purported assignment shall be void, except that Aerogen may assign its rights and obligations pursuant to merger, acquisition or sale of all or substantially all of the assets of Aerogen relating to the Product. This Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties.

14.9 Notices. Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement and shall be deemed to have been sufficiently given for all purposes (a) five (5) days after mailing by registered first class mail, (b) two (2) days after sending by international express delivery service, (c) the same day if sent by facsimile transmission, with transmission confirmed or (d) immediately if personally delivered. Unless otherwise specified in writing, the mailing addresses and facsimile numbers of the Parties shall be as described below.

To MIA: Medical Industries America, Inc.
2636 289th Place
Adel, IA 50003
Attn: Chief Executive Officer
Fax: (515) 993 4172

To Aerogen: Aerogen, Inc.
2071 Stierlin Court,
Mountain View, CA 94043
Attn: Chief Financial Officer
Fax: (650) 864 7433

For notices relating to Product complaints, and reportable events pursuant to **Section 7.2**, such notices shall be directed to the Vice President of Regulatory Affairs and Quality at Aerogen.

14.10 Construction. The section headings are inserted for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement. As used in this Agreement, the word "including" means "including but not limited to". All references to Aerogen mean Aerogen, Inc. and its Affiliates. In constructing the terms of this Agreement, no presumption will operate in favor of or against any Party as a result of its counsel's role in drafting the terms and provisions hereof.

14.11 Independent Contractors. In making and performing this Agreement, Aerogen and MIA shall act at all times as independent contractors and nothing contained in this Agreement shall be construed as to create an agency, partnership or employer and employee relationship between Aerogen and MIA.

14.12 Waiver. No waiver of any right under this Agreement shall be deemed effective unless contained in a writing signed by the Party charged with such waiver, and no waiver of any

right arising from any breach or failure to perform shall be deemed to be a waiver of any future such right or of any other right arising under this Agreement.

<< SIGNATURE PAGE FOLLOWS >>

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IN WITNESS WHEREOF, both Aerogen and MIA have executed this Agreement by their duly authorized officers as of the Effective Date.

AEROGEN, INC.

MEDICAL INDUSTRIES AMERICA, INC.

/s/ Robert S. Breuil

/s/ Russell Bird

Name: Robert Breuil
Title: Chief Financial Officer

Name: Russell Bird
Title: President

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