18-03592-E

March 28 2018

US Securities & Exchange Commission Office of FOIA and Privacy Act Operations 100.F Street, NE Mail Stop 5100 Washington, DC 20549-5100 RECEIVED

MAR 28 2018

Office of FOIA Services

Dear FOIA Office:

Under the Freedom of Information Act (FOIA), please send a copy of the following:

A copy of: Exhibit 10.54 to the form 10-K/A filed by ANTARES PHARMA INC on May 5, 2006

In the event confidential treatment has not expired provide the specific date for which confidential treatment is still in effect. I do not need a copy of the order. We authorize up to

Paul D'Souza

**Editor - Deals** 

Clarivate Analytics Friars House, 160 Blackfriars Road London, UK SE1 8EZ

Phone: +44-2074334789 paul.dsouza@clarivate.com

\$61.00 in processing fees. Thank You,



### UNITED STATES SECURITIES AND EXCHANGE COMMISSION

STATION PLACE 100 F STREET, NE WASHINGTON, DC 20549-2465

Office of FOIA Services

April 3, 2018

Mr. Paul D'Souza Clarivate Analytics 160 Blackfriars Road London, SE1 8EZ United Kingdom

RE: Freedom of Information Act (FOIA), 5 U.S.C.  $\S$  552

Request No. 18-03592-E

Dear Mr. D'Souza:

This letter is in response to your request, dated and received in this office on March 28, 2018, for access to Exhibit 10.54 to the Form 10-K/A filed by Antares Pharma, Inc. on May 5, 2006.

The search for responsive records has resulted in the retrieval of 22 pages of records that may be responsive to your request. They are being provided to you with this letter.

No fees have been assessed for the processing of this request. If you have any questions, please contact me at <a href="mailto:taylorf@sec.gov">taylorf@sec.gov</a> or (202) 551-8349. You may also contact me at <a href="mailto:foiapa@sec.gov">foiapa@sec.gov</a> or (202) 551-7900. You also have the right to seek assistance from Dave Henshall 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 <a href="mailto:Archives.gov">Archives.gov</a> or via e-mail at <a href="mailto:ogis@nara.gov">ogis@nara.gov</a>.

Sincerely,

Felecia Taylor

FOIA Lead Research Specialist

Enclosure

#### LICENSE, DEVELOPMENT AND SUPPLY AGREEMENT

THIS LICENSE, DEVELOPMENT AND SUPPLY AGREEMENT (the "Agreement"), dated as of November 23, 2005, (the "Effective Date") entered into between SICOR PHARMACEUTICALS, INC., a Delaware corporation ("Teva / Sicor"), having a place of business located at 19 Hughes, Irvine, California 92618, and ANTARES PHARMA, INC., a Delaware corporation ("Antares"), having a place of business located at 707 Eagleview Boulevard, Suite 414, Exton, Pennsylvania 19341,

#### WITNESSETH:

WHEREAS, Antares owns or has rights to certain technology which may be used in the manufacture of a fixed-dose, single-dose disposable mini-needle injector for the delivery of sumatriptan; and

WHEREAS, Antares and Teva / Sicor desire to collaborate in the development and commercialization of the Device on the terms and subject to the conditions set forth below; and

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

## ARTICLE 1 DEFINITIONS

For purposes of this Agreement, the terms defined in this Article 1 have the meanings set forth below:

- 1.1 "Affiliate" means, with respect to any Person, any other Person which directly or indirectly controls, is controlled by, or is under common control with, such Person. A Person shall be regarded as in control of another Person if it owns, or directly or indirectly controls, at least fifty percent (50%) of the voting stock or other ownership interest of the other Person, provided that such entity shall be considered an Affiliate only for the time during which such control exists.
- 1.2 "ANDA" means an Abbreviated New Drug Application for the Product which has been or will be submitted to the FDA pursuant to 21 U.S.C. § 355(j) and the regulations promulgated by the FDA thereunder, including any amendments or supplements thereto.
- 1.3 "Antares Patent Rights" means all issued patents and patent applications, divisionals, continuations, continuations-in-part, reissues, renewals, extensions or additions to any such patent applications or patents heretofore or hereafter filed in any country in the Territory owned by or licensed to Antares or to which Antares otherwise acquires rights, which claim the Device, or the process of manufacture or use of the Device in the Territory.
- 1.4 "ASP" means Teva / Sicor's average Net Sales price for a single unit of the Product during a calendar quarter.

- 1.5 "cGMP" means current Good Manufacturing Practices as promulgated by the FDA and set forth in 21 CFR Parts 210 and 211.
- 1.6 "Change of Control" shall mean, with respect to the applicable Party, an event where: (a) any Third Party (alone or together with such Third Party's Affiliates) or "group" (as such term is defined under Section 13(d) of the Securities Exchange Act of 1934, as amended) (i) acquires beneficial ownership of capital stock of such Party entitling the holder(s) thereof to greater than fifty percent (50%) of the voting power of the then outstanding capital stock of such Party with respect to the election of directors of such Party, or (ii) otherwise actually controls or is in a controlling position with respect to the voting power of the then outstanding capital stock of such Party; or (b) such Party consummates a merger, consolidation, reorganization or similar transaction or series of related transactions, whether direct or indirect, with another Third Party, alone or together with such Third Party's Affiliates (the "Acquiring Corporation"), in which: (i) such Party is not the surviving corporation in such transaction, (ii) the members of the Board of Directors of such Party prior to such transaction constitute less than one half of the members of the Board of Directors of the Acquiring Corporation following such transaction, (iii) greater than fifty percent (50%) of the voting power of the outstanding capital stock of the Acquiring Corporation with respect to the election of directors following such transaction is held by Third Parties who were shareholders of the Acquiring Corporation prior to such transaction, or (iv) such Party is otherwise effectively controlled by the Acquiring Corporation, or (c) such Party sells to any Third Party(s) (alone or together with such Third Party's Affiliates) in one or more related transactions properties or assets representing greater than fifty percent (50%) of: (i) such Party's consolidated total assets as reflected on its most recent annual audited financial statements, provided that all or substantially all of the properties and assets used in connection with such Party's pharmaceutical business are included in such transaction(s), or (ii) such Party's pharmaceutical business. Notwithstanding anything to the contrary in this definition, a Change of Control shall not be deemed to have occurred with respect to a Party where any acquisition, merger, consolidation, reorganization, sale or similar transaction occurs solely between such Party and any one or more of its Affiliates.
- 1.7 "Confidential Information" means any invention, discovery, patent application or claim, trade secret, idea, improvement or other work of authorship, any process, formula, data, clinical trial data, program, drawing, information, price, technique, sample, compound, extract, media, vector or cell line and procedures and formulations or drawings for producing any such sample, compound, extract, media, vector or cell line, any process, formula or data relating to any research project, work in process, future development, engineering, manufacturing, marketing, servicing, financing or personnel matter relating to a Party, its present or future products, sales suppliers, clients, customers, employees, investors, or business, whether in oral, written, graphic, physical or electronic form.
- 1.8 "Contract Margin" means Net Sales of the finished Product less Teva / Sicor's acquisition cost (Unit Price times number of units purchased) for the Device.
- 1.9 "<u>Device</u>" means a fixed-dose, single-dose disposable mini-needle injector that accommodates a Becton Dickinson 1mL "long" glass Hypak<sup>®</sup> syringe. The Device is intended to be supplied as two sub-assemblies, and does not include the glass syringe, stopper, or needle cap.

- 1.10 "Drug" means sumatriptan used for the treatment of migraines in humans.
- 1.11 "FDA" means the United States Food and Drug Administration.
- 1.12 "Field" means the delivery of the Drug for the treatment of migraines in humans.
- 1.13 "Know-How" means all information and data, including formulas, procedures, protocols, techniques and results of experimentation and testing, which are necessary or useful to make, use, develop, sell or seek regulatory approval in the Territory to market the Product, which Antares owns or controls, has the right to license to Teva / Sicor, and which is in the possession of Antares on the Effective Date of this Agreement or thereafter during the term of this Agreement.
- 1.14 "<u>Licensed Technology</u>" means the Antares Patent Rights together with all improvements to the Licensed Technology relating to the Device developed by Antares during the term of this Agreement.
- 1.15 "MAF" means the master access file to be submitted by Antares to the FDA Center for Devices and Radiological Health with respect to the Device.
- 1.16 "Net Sales" means, with respect to Product sold by Teva / Sicor or its Affiliates to Third Parties, the aggregate gross sales of the amounts invoiced for the Product in arm's length transactions with third parties ("Gross Sales") in the Territory, less the following deductions: (a) two percent (2%) of Gross Sales to cover cash discounts; (b) any adjustments actually allowed and granted to customers on account of price adjustments, shelf stock adjustments, billing adjustments, shortages, promotional payments, and rejected, damaged and returned goods; (c) reasonable estimates for chargebacks, rebates, administrative fee arrangements, reimbursements, and similar payments to wholesalers or distributors, buying groups, health care insurance carriers, pharmacy benefit management companies, health maintenance organizations, other institutions or customers, determined in a manner consistent with Teva / Sicor's practice for its other pharmaceutical products; and (d) two percent (2%) of Gross Sales of Product sold to any governmental or regulatory authority in respect of state or federal Medicare, Medicaid or similar programs to cover rebates or other price reductions provided.
- 1.17 "Paragraph III Certification" means a certification pursuant to section 505(j)(2)(A)(vii)(III) of the Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(III).
  - 1.18 "Party" means either Antares or Teva / Sicor respectively.
- 1.19 "Person" means an individual, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, governmental authority or any other form of entity specifically listed herein.
  - 1.20 "Product" means any product comprising the Device and the Drug.
- 1.21 "OSR" means the Quality System Regulation as promulgated by the FDA and set forth in 21 CFR Part 820.

- 1.22 "Teva / Sicor Patent Rights" means all issued patents and patent applications, divisionals, continuations, continuations-in-part, reissues, renewals, extensions or additions to any such patent applications or patents heretofore or hereafter filed in any country in the Territory owned by or licensed to Teva / Sicor or any of its Affiliates or to which Teva / Sicor or any of its Affiliates otherwise acquires rights, which claim the Drug, or the process of manufacture or use of the Drug in the Territory.
- 1.23 "<u>Territory</u>" means the United States of America, including its territories, possessions and the Commonwealth of Puerto Rico.
- 1.24 "Third Party" means any Person other than Teva / Sicor, Antares and their respective Affiliates.
  - 1.25 "Unit Price" means Teva / Sicor's purchase price for a single unit of the Device.

## ARTICLE 2 REPRESENTATIONS AND WARRANTIES

- 2.1 <u>Representations by Each Party</u>. Each Party hereby represents and warrants to the other Party, as of the execution of this Agreement, as follows:
- 2.1.1 Corporate Existence and Power. Such Party (a) is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is incorporated; (b) has the corporate power and authority and the legal right to own and operate its property and assets, to lease the property and assets it operates under lease, and to carry on its business as it is now being conducted; and (c) is in compliance with all requirements of applicable law, except to the extent that any noncompliance would not have a material adverse effect on the properties, business, financial or other condition of such Party and would not materially adversely affect such Party's ability to perform its obligations under this Agreement.
- 2.1.2 <u>Authorization and Enforcement of Obligations</u>. Such Party (a) has the corporate power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder, and (b) has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. The Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms.
- 2.1.3 <u>Consents</u>. All necessary consents, approvals and authorizations of all governmental authorities and other Persons required to be obtained by such Party in connection with this Agreement have been obtained.
- 2.1.4 No Conflicts. The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (a) do not conflict with or violate any requirement of applicable laws or regulations, and (b) do not conflict with, or constitute a default under, any contractual obligation of such Party.
- 2.2. <u>Representations of Antares</u>. Antares hereby represents and warrants to Teva / Sicor that Antares is either in sole possession of or otherwise possesses all necessary consents,

approvals and authorizations to the Licensed Technology to grant the license set forth in Article 3 hereof to Teva / Sicor.

### ARTICLE 3 LICENSE GRANT

- 3.1 <u>License</u>. Subject to the terms and conditions of this Agreement, during the term of this Agreement, Antares hereby grants to Teva / Sicor and its Affiliates an exclusive license (exclusive even as to Antares), with the right to sublicense (subject to the provisions of section 3.2), under the Antares Patent Rights and Know How to use the Device in the Product and to sell, offer for sale, import and distribute the Product in the Field in the Territory.
- 3.2 <u>Sublicenses</u>. Teva / Sicor may grant sublicenses in the Territory, provided that Teva / Sicor shall ensure all such sublicensees assume and comply with all terms and conditions under which Teva / Sicor is obligated as a licensee under this Agreement. Teva / Sicor shall indemnify and hold Antares harmless from any cost, liability, or damage arising from any sublicensee's failure to so comply. Teva / Sicor shall pay Antares forty percent (40%) of all consideration, whether in cash or kind, paid to Teva / Sicor for granting each such sublicense within forty-five (45) days of Teva / Sicor's receipt of any such consideration.
- 3.3 Exclusivity. Subject to the provisions of section 10.2.3 hereof, during the term of this Agreement, neither Party or any of its Affiliates, either alone or through any Third Party, will develop, manufacture for use in the Field and the Territory or commercialize any device or product comprised of a mini-needle injector and the Drug which competes with the Product in the Field and the Territory except pursuant to this Agreement.
- 3.4 Right of First Refusal. Antares shall promptly notify Teva / Sicor in writing before offering a license to the Device for use in the Field to a Third Party in a country outside the Territory. Teva / Sicor shall have thirty (30) days from receipt of such notice in which to negotiate a non-binding term sheet with Antares for an exclusive license to the Device for use in the Field in such country or countries. If the parties are unable to reach agreement on such non-binding terms within such thirty (30) day period, Antares may negotiate and execute a license with a Third Party, but not on terms any less favorable to Antares than the terms last offered by Teva / Sicor. If the Parties agree in writing to such non-binding terms within such thirty (30) day period, Teva / Sicor shall have sixty (60) days following immediately from such thirty (30) day period in which to negotiate and enter into an exclusive license with Antares for the Device in such country or countries, as the case may be. All negotiations shall be conducted in good faith. If the parties do not enter into such a license within such sixty (60) day period, Antares may negotiate and execute a license with a Third Party, but not on terms any less favorable to Antares than the terms last offered by Teva / Sicor.
- 3.5 Additional License in the Event of Failure to Supply. In the event that Antares is unable to supply conforming Devices to Teva / Sicor in connection with an accepted purchase order pursuant to Article 5 hereof, with such failure remaining uncured for thirty (30) days, then Antares hereby grants to Teva / Sicor a royalty-bearing right and license in the Territory to (i) make and have made the Device for use in the Product in the Field in the Territory, and (ii) use and reference the necessary regulatory documentation, and any and all data or information

included or referenced therein, to make or have made the Device. For any Device manufactured by Teva / Sicor pursuant to this Section, Teva / Sicor shall pay Antares the royalties due under Section 7.1 hereof. If thereafter Antares notifies Teva/Sicor that Antares is able to supply conforming Devices again pursuant to Article 5 hereof, then Antares shall provide notice of the same to Teva / Sicor and Antares shall resume its supply of Devices as provided in this Agreement. Upon Antares' resumption of such supply, the foregoing license granted to Teva / Sicor in this Section shall immediately terminate and be of no further force or effect.

### ARTICLE 4 DEVELOPMENT PROGRAM AND MILESTONE PAYMENTS

- 4.1 <u>Development Program.</u> Promptly upon execution of this Agreement, the Parties shall commence a development program (the "Program"), which shall be designed to complete the Device development and to scale-up the Device for commercial production for use with the Drug in the Product. The Program will include finalizing a Product specification which shall not be materially dissimilar to the AJ-ES device previously presented to Teva / Sicor. Once the Product specifications are finalized by agreement of the Parties, any additional changes to the Device requested by Teva / Sicor must be agreed to by Antares. Teva / Sicor will provide Antares with all change requests in writing. Antares will provide Teva / Sicor with an estimate of cost and time required to implement any changes, and Teva / Sicor will be responsible for all such costs.
- 4.1.1 Antares' Responsibilities. Antares will be responsible for the payment of development expenses required to complete the development activities identified in the Program, and for capital equipment costs necessary to scale up to meet commercial production demand of up to one million units per year. Antares will maintain its MAF, and any other required regulatory submissions and approvals, in good standing, and maintain its facilities in compliance with QSR.
- 4.1.2 <u>Teva / Sicor's Responsibilities</u>. Once the Product specifications are finalized, Teva / Sicor will be responsible for any additional development expenses, additional capital equipment costs, and any Device price increases due to changes in the Product definition implemented in accordance with the terms set forth in section 4.1 above, including the development of any additional components related to the Device such as a case.
- 4.1.3 Additional Costs. Any costs incurred by Antares to accelerate the Program at the request of Teva / Sicor will be borne by Teva / Sicor. Any increased costs directly related to development of the Sumatriptan Product incurred by Teva / Sicor as a result of delays in the development or scale-up of the Device due to Antares' failure to meet their obligations in the schedule set forth in the Program will be borne by Antares.

#### 4.2 Payments By Teva / Sicor.

4.2.1 Payments Upon Execution of This Agreement. Upon the execution and delivery of this Agreement, Teva / Sicor shall pay to Antares the sum of (a) five hundred

thousand dollars (\$500,000) in exchange for 400,000 shares of Antares common stock, subject to the Stock Purchase Agreement executed by the Parties contemporaneously herewith and attached as Exhibit "A" hereto; and (b) two hundred fifty thousand dollars (\$250,000) against royalties owing, in exchange for the exclusive license set forth in Section 3.1 hereof.

- 4.2.2 Milestone Payment. Upon final FDA approval of the Product, Teva / Sicor shall pay to Antares the sum of \$250,000.
- 4.2.3 Payment Recovery. After Teva / Sicor has paid royalties to Antares in accordance with the terms set forth in Article 7 herein totaling \$750,000, Teva / Sicor will withhold and retain for its own account up to \$50,000 in royalty payments in each subsequent quarter until a cumulative total of \$250,000 in royalty payments has been withheld. Full royalty payments to Antares will resume after Teva / Sicor has withheld and retained \$250,000 in royalty payments.

# ARTICLE 5 COMMERCIAL SUPPLY OF DEVICE

- 5.1 <u>Device Supply.</u> Upon FDA approval of the Product, Antares will be the exclusive provider of the Device to Teva / Sicor in accordance with the terms and conditions set forth in this Agreement, and such other commercially reasonable terms and conditions as the Parties shall in good faith negotiate and agree to in writing including, but not limited to, specifications for the Device, warranty terms, and other customary terms and conditions. Teva / Sicor will commercially market the Product incorporating the Device produced by Antares, and Teva / Sicor will be responsible for the production of the Drug, including but not limited to fill and finish, the final assembly of the Product, and final packaging and labeling.
- 5.2 Forecasts and Delivery. On or before the 20th day of the third month of each calendar quarter (i.e., March 20, June 20, September 20 and December 20) Teva / Sicor will provide Antares with a rolling quarterly forecast for the Device for the next six (6) calendar quarters. Forecasted unit demand set forth in the first two (2) quarters of each rolling quarterly forecast will represent a firm purchase commitment. The last four (4) quarters will represent a non-binding, good faith estimate of Teva / Sicor's expected requirements for the Device. If any rolling quarterly forecast results in a quarter-to-quarter increase of 250,000 or more units, or if the forecasted number of units exceeds one million (1,000,000) units in total for any consecutive four-quarter period, the Parties agree to negotiate in good faith terms and conditions under which Antares will expand its manufacturing capacity to achieve the incremental forecasted volumes.
- 5.2.1 <u>Purchase Orders</u>. With each rolling quarterly forecast, Teva / Sicor will submit a firm purchase order for Devices needed during the second calendar quarter in the current rolling quarterly forecast. (A purchase order for Devices to be delivered in the first calendar quarter of the current rolling quarterly forecast will have been submitted with the prior forecast.) Each purchase order must specify unit quantity, delivery dates, delivery instructions, Unit Price and other applicable invoice information as agreed by the Parties in writing ("Accepted Purchase Order"). Changes will not be allowed to any Accepted Purchase Order

unless agreed in writing by the Parties. The terms and conditions of this Agreement shall govern each purchase order, and in the event of conflict the terms and conditions of this Agreement shall prevail.

- 5.2.2 Master Forecast. The rolling quarterly forecast submitted in September of each calendar year shall be considered the master forecast for the following calendar year. Invoice pricing for Devices to be delivered in the next calendar year shall be determined by matching the units forecasted in the master forecast to the corresponding Unit Price contained in the price schedule set forth in section 5.3 herein. Subject to Section 5.2.2.1 herein, should Teva / Sicor's actual Device purchases in a calendar year differ from those set forth in the master forecast such that a higher or lower price should have been paid, this difference shall be determined within 60 days after the end of the applicable calendar year and applied as a credit or debit against royalties payable in subsequent periods.
- 5.2.2.1 No price reconciliation will be made pursuant to Section 5.2.2 as a result of; (a) increases in actual versus forecasted volumes until after the first calendar year with at least six (6) consecutive months of commercial sales of a Product, or (b) increases in actual versus forecasted volumes due to; (i) changes in any Accepted Purchase Order, (ii) additional purchase orders submitted for the current or next quarter after an Accepted Purchase Order exists for such quarter, or (iii) a change from Standard Pricing to Reduced Pricing.
- 5.2.3 <u>Invoices</u>. Teva / Sicor shall pay each invoice within thirty (30) calendar days from the date of receipt of the Devices. Antares shall invoice Teva / Sicor at the time of shipment of the Devices to Teva / Sicor, which shall be EXW Antares' manufacturing facility (Incoterms 2000). All transportation and insurance costs for the Devices from Antares' manufacturing facility shall be paid by Teva / Sicor.
- 5.2.4 <u>Acceptance</u>. Antares will deliver to Teva / Sicor a certificate of conformance with each shipment of Devices confirming that all Devices conform to the specifications. Teva / Sicor shall have forty-five (45) calendar days after the delivery date to notify Antares that Devices received were defective or non-conforming. In such case, the parties shall use good-faith efforts to resolve the problem.
- 5.3 <u>Standard Pricing</u>. The Standard Pricing for the Device supplied by Antares to Teva / Sicor will be as follows:

Annual units Unit Pr	
0.25M up to 0.5M \$6.25	
0.5M up to 1.5M \$5.35	
1.5M up to 2.0M \$4.85	
above 2.0M \$4.25	

5.4 Reduced Pricing. In the event that competition from other injectable sumatriptan products leads Teva / Sicor in good faith to substantially discount its pricing of the Product, Antares will (upon receipt of satisfactory evidence of such pricing competition, and during the

period of such discounting by Teva / Sicor) provide Reduced Pricing to Teva / Sicor in accordance with the schedule below:

ASP
Unit Price
\$20.00 or higher
Standard Pricing
Less than \$20.00 the greater of (a) 20% of the ASP for the
Sumatriptan Product, or (b) Antares' fully burdened
cost (as defined in section 10.2.3(x) hereof) of the
Device plus 15%, but not to exceed \$3.90.

- 5.5 Adjustments to Pricing. The pricing set forth in sections 5.3 and 5.4 applies only to the Device, to be supplied as two sub-assemblies. It does not include a case or other component to allow multiple devices to be held together. All prices may be increased by Antares at a rate not to exceed the increase versus prior year in the latest version of the Producer Price Index data for finished goods (not seasonally adjusted) published by the U.S. Department of Labor, Bureau of Labor Statistics, as of the date specified for such calculations, once per year commencing on the first anniversary of the date of this Agreement. Additionally, if Antares experiences an actual increase of more than seven percent (7%) in its cost of supplying the Device within a 12-month period and from the most recent price adjustment, or if actual costs increase by more than fifteen percent (15%) on a cumulative basis over three (3) consecutive calendar years during the Term, the parties agree to negotiate in good faith to establish revised pricing for the Device.
- 5.6 <u>Qualification of Backup Suppliers</u>. Notwithstanding section 5.1 hereof, Teva / Sicor shall have the right at any time during the term of this Agreement to qualify and contract with one or more backup suppliers (including Antares' existing supplier) for the Device, in order to enable Teva / Sicor to timely exercise its rights under section 3.5 of the Agreement. Antares shall reasonably cooperate with Teva / Sicor in qualifying such backup suppliers, including, without limitation, providing appropriate technical information, subject to the execution of reasonable confidentiality agreements.
- 5.7 Loss of Exclusivity. If Teva / Sicor's sales of the Product (including sales of the Product by Teva / Sicor's sublicensees) fall below 62,500 units per quarter for any two calendar quarters beginning 12 months after the launch of the Product, Antares will, at its sole discretion, have the right to convert the exclusive license granted hereunder to a non-exclusive license.

## ARTICLE 6 REGULATORY SUBMISSIONS

- 6.1 <u>Teva / Sicor's Responsibilities</u>. Teva / Sicor is responsible for preparing, prosecuting, and maintaining registrations, filings and approvals relating to the Drug and the Product, and will be responsible for its own internal and external expenses related to regulatory submissions and approvals of the Drug and the Product.
- 6.2 <u>Antares' Responsibilities</u>. Antares is responsible for preparing, prosecuting, and maintaining registrations, filings and approvals relating to the Device and will be responsible for

its own internal and external expenses related to regulatory submissions and approvals for the Device.

Adverse Experience Reporting. Teva / Sicor and Antares shall report to the other 6.3 any information of which they have knowledge concerning any adverse drug experience in connection with the use of the Product, including the incidence or severity thereof, whether or not determined to be attributable to the Product. Reports of routine adverse drug experiences of the type defined in Section 314.80 of Title 21 of the United States Code of Federal Regulations shall be exchanged by each Party on a quarterly basis. Reports of serious adverse drug experiences of the type defined in Sections 312.32 and 314.80 of Title 21 of the United States Code of Federal Regulations shall be made available to the other Party within five (5) days after a Party becomes aware of such serious adverse drug experience. Upon receipt of any such information concerning any serious adverse drug experience by either Teva / Sicor or Antares, the Parties shall promptly consult each other and use their best efforts to arrive at a mutually acceptable procedure for taking such possible actions as appropriate or required under the circumstances; provided, however, that nothing contained herein shall be construed as restricting the right or duty of either Party to make a required report or submission to the FDA or take any other action that it deems to be appropriate or required by applicable law or regulation. In any event, the responsibility of making any reports of adverse drug experience or other required reports to the FDA shall be upon the holder of the product registration for the Product.

#### 6.4 Recall Action.

- 6.4.1 In the event Teva / Sicor is required or voluntarily decides to initiate a recall, withdrawal, or field correction of the Product, Teva / Sicor shall notify Antares and provide a copy of its proposal, including the recall letter. In conjunction with such recall, Antares at Teva / Sicor's sole expense shall assist in the investigation to determine the cause and extent of the problem, unless it is subsequently determined that such recall was necessitated entirely by the negligence or intentionally wrongful act of Antares or its representatives, in which case such assistance shall be at Antares' sole expense.
- 6.4.2 In the event that Antares independently believes that a recall, withdrawal, or field correction of the Product may be necessary or appropriate, Antares shall notify Teva / Sicor of Antares' belief, and the Parties shall fully cooperate with each other concerning the necessity and nature of such action, provided that, in the event that the Product is recalled as a result of the negligent or intentionally wrongful act of Teva / Sicor or its representatives, any expenses incurred by Antares in connection with such cooperation, including, but not limited to, outside expert fees and reasonable legal fees, shall be borne by Teva / Sicor.
- 6.4.3 All coordination of any recall, withdrawal or field correction activities involving the Product shall he handled by Teva / Sicor, who shall keep Antares promptly advised of all matters relating thereto, whether or not such action was initially requested by Antares. Unless required by applicable law or regulation, or unless due to a defect in the Device, Teva / Sicor will not disclose or refer to Antares in connection with a recall, withdrawal or field correction without Antares' prior written consent.

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- Expenses. In the event that the Product is recalled as a result of the negligent or 6.5 intentionally wrongful act of Teva / Sicor or its representatives, then Teva / Sicor shall bear all of the costs and expenses of such recall, including, without limitation, expenses related to communications and meetings with all required regulatory agencies, expenses of replacement stock, the cost of notifying customers and costs associated with shipment of recalled Product from customers and shipment of an equal amount of replacement Product to those same customers. In the event that the Product is recalled as a result of the negligent or intentionally wrongful act of Antares or its representatives, then Antares shall bear all of the costs and expenses of such recall, including expenses related to communications and meetings with all required regulatory agencies, expenses of replacement stock, the cost of notifying customers and costs associated with shipment of recalled Product from customers and shipment of an equal amount of replacement Product to those same customers. To the extent that the reason for any recall of the Product hereunder is in part the responsibility of Antares and in part the responsibility of Teva / Sicor, then the expenses shall be equitably allocated between the Parties. Applicable recall costs payable by Antares may be offset against future royalty payments.
- 6.6 <u>Recall Records</u>. Teva / Sicor shall maintain complete and accurate recall records for such periods as may be required by applicable law, but in no event less than three (3) years, of all Product sold by it.

## ARTICLE 7 ROYALTIES

- 7.1 Royalty. In consideration of the license granted pursuant to Section 3.1, Teva / Sicor shall pay Antares, within forty-five (45) days of the end of each calendar quarter during the term hereof, subject to section 4.2.3 hereof, a royalty on commercial sales of Product in the Territory of (a) 2% of Contract Margin on the first 500,000 units of Product sold in any calendar year; (b) 5% of Contract Margin on the next 500,000 units of Product sold in any calendar year; and (c) 8% of Contract Margin on Product sold in excess of 1,000,000 units in any calendar year. During the year in which the Product is first marketed, the unit quantities set forth above shall be pro rated based on the number of days in the year during which the Product is marketed. Late payments shall accrue interest at a rate of one percent (1%) per month.
- 7.2 Adjustments. In the event that Antares is unable to supply conforming Devices in quantities and at times reasonably requested by Teva / Sicor and in accordance with the lead times agreed by the Parties for thirty (30) days beyond Teva / Sicor's requested delivery date as specified in Teva / Sicor's purchase order, the royalty due Antares will be reduced by 50% with respect to all deliveries affected by the supply interruption until (a) Antares satisfies all Teva / Sicor backorders and (b) current deliveries are on time.
- 7.2.1 Commercial Launch. In the event that Antares is unable to supply conforming Devices at the time and in the quantity requested by Teva/Sicor for its commercial launch of the Product for reasons other than (i) failure of the Parties to reach agreement on (A) a product specification and development timetable pursuant to Section 4.1 above, or (B) the quantity to be supplied for commercial launch, (ii) Teva / Sicor's failure to meet its obligations set forth in this Agreement, (iii) termination of the Agreement for any reason, or (iv) force majeure (except that, for purposes of this subsection 7.2.1, "force majeure" shall mean only

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earthquake, fire, floods, war, acts of war (whether war be declared or not), weather conditions, or other acts of God), Antares shall pay Teva/Sicor \$500,000, if forecasts and purchase orders were provided to Antares in accordance with the terms set forth in Article 5 of this Agreement. This amount shall be in addition to any Adjustments payable in accordance with the terms and conditions set forth in Section 7.1 above, and in addition to any other remedies Teva/Sicor may have pursuant to this Agreement or otherwise, but shall be reduced by any amounts payable by Antares pursuant to Section 4.1.3 hereof.

- 7.3 Taxes. All federal, state, district, local or other governmental authority income or similar tax measured by income that is imposed on either Party as a result of income generated as a result of the transactions contemplated under this Agreement, shall be the responsibility of such Party. Any federal, state, district, local or other governmental authority sales or use tax, excise or similar tax assessed on the sale of the Product by Teva / Sicor shall be paid by Teva / Sicor.
- 7.4 <u>Customer Pricing</u>. Teva / Sicor shall have sole discretion in setting customer pricing for the Product.
- Records; Audit. Teva / Sicor shall keep books and records in the normal course 7.5 of business in the Territory identifying annual (on a calendar year basis) sales of the Product in units and values. Net Sales and deductions therefrom, gross revenue received, cost of goods sold, credits applied for returned units, and the amounts due Antares. Teva / Sicor shall maintain such books and records for two (2) years from the date of payment or until any relevant dispute has been resolved, whichever is longer. Upon Antares' reasonable request, and at Antares' sole expense, but no more than once each calendar year during the term of the Agreement, Teva / Sicor shall permit an independent certified public accountant to examine such books and records on behalf of Antares upon reasonable notice during normal business hours. Such independent certified public accountant shall sign a confidentiality and non-disclosure agreement in form and substance reasonably satisfactory to Teva / Sicor and shall not disclose to Antares or any Third Party any information other than the amount of any inaccuracy. The report prepared by such accountant shall not disclose to Antares or to any Third Party any information except that which should properly be contained in a royalty report required under Section 7.1 hereof and such other information as reasonably shall be necessary to verify the calculation of the Net Sales. A complete copy of the report of such accountant shall be given to Teva / Sicor at the same time that it is provided to Antares. If, as a result of any such examination, it is shown that Teva/ Sicor's payments to Antares under this Section were less than the amount which should have been paid, then Teva / Sicor shall make all payments required to be made to eliminate any discrepancy revealed by the examination within thirty (30) days after Antares' demand therefor and, if such discrepancy exceeds ten percent (10%) of amounts paid to Antares, Teva / Sicor shall reimburse Antares for all costs and expenses incurred by Antares to perform the audit. The interest charged on overdue payments pursuant to Section 7.1 hereof shall apply to any underpayments due from Teva / Sicor. Any overpayments shall be fully reimbursed to Teva / Sicor within thirty (30) days after Teva / Sicor's demand therefor. Antares agrees that all information subject to review under this Section 7.5 or under any sublicense or supply agreement is confidential and that Antares shall retain and shall cause its accountant to retain all such information in confidence.

ARTICLE 8

#### CONFIDENTIALITY

- 8.1 Confidentiality Obligation. During the term of this Agreement, and for a period of seven (7) years following the expiration or earlier termination hereof, the receiving Party (the "Receiving Party") will not publish or otherwise disclose to any Third Party absent an express written agreement permitting such disclosure and will not use for any purpose other than as provided in this Agreement, any and all Confidential Information received from the other Party (the "Disclosing Party") on a confidential basis. Each Party shall use the same degree of care, which shall not be less than a reasonable degree of care, that it uses to protect its own confidential information to prevent the unauthorized disclosure of Confidential Information. The foregoing confidentiality obligation shall not apply to information which: (i) at the time of the disclosure to the Receiving Party was in the public domain, or (ii) after disclosure, becomes part of the public domain through no fault of the Receiving Party or any act or omission of the Receiving Party in breach of this Agreement, or (iii) was previously known to the Receiving Party from a source other than the Disclosing Party and such source was under no obligation to keep such information confidential or which is received from a Third Party, provided said party did not obtain it directly or indirectly from the Disclosing Party or a party who was under a duty to keep such information confidential, or (iv) was independently developed or discovered by the Receiving Party without the use of Confidential Information belonging to the Disclosing Party. Notwithstanding anything herein contained to the contrary, all Confidential Information previously disclosed by Antares shall continue to be subject to the Confidential Disclosure Agreement dated December 20, 2002 between the Parties, which shall survive the execution and termination of this Agreement.
- 8.2 Authorized Disclosure. Each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary for (a) filing or prosecuting patents relating to the Device or the Product; (b) regulatory filings; (c) prosecuting or defending litigation; (d) complying with applicable governmental regulations; (e) conducting pre-clinical or clinical trials of Products; (f) disclosure on a need to know basis to Affiliates, sublicensees, employees, consultants or agents who agree to be bound by similar terms of confidentiality and non-use at least equivalent in scope to those set forth in this Article 8; and (g) use of jointly owned Inventions and Technology.
- 8.3 Other Permitted Disclosure. Except as otherwise provided in Section 8.3 of this Agreement, either Party (the "Publishing Party") may use or refer to the name of the other Party: (i) in connection with the Publishing Party's efforts to secure financing at any time during the term of this Agreement; (ii) in connection with a press release regarding this Agreement and the relationship of the Parties created hereby, which shall be mutually agreed upon by the Parties; or (iii) in statements that the Publishing Party reasonably determines to be necessary to comply with applicable law (including the disclosure requirements of the U.S. Securities and Exchange Commission or under applicable Blue Sky laws (for private financings or public financing), Nasdaq or any other stock exchange on which securities issued by the Publishing Party are traded); provided, however, that to the extent practicable under the circumstances, the Publishing Party shall provide the other Party with a copy of the proposed text of such statements sufficiently in advance of the scheduled release thereof to afford such other Party a reasonable opportunity to review and comment upon the proposed text. Except as permitted in this provision, neither Party shall disclose, use or refer to, without the other Party's prior written

consent which consent shall not be unreasonably withheld or delayed, the name or trademarks of such other Party in any public statements, whether oral or written, including-shareholder reports, communications with stock market analysts or other communications with the media, or prospectuses.

8.4 <u>Publications</u>. If either Party desires to disclose any information which relates to the Device or the Product in scientific journals, publications or scientific presentations or otherwise, the Publishing Party will provide the other Party an advance copy of any proposed publication or summary of a proposed oral presentation prior to submission for publication or disclosure. Such other Party will have a reasonable opportunity to recommend any changes it reasonably believes necessary.

### ARTICLE 9 PATENT RIGHTS

- 9.1 Ownership. As between Antares and Teva / Sicor, (a) the entire right and title in all inventions, discoveries, improvements or other technology directed to the manufacture or use of the Drug, and all processes relating thereto, whether or not patentable, and any patent applications or patents based thereon (the "Teva / Sicor Inventions"), shall be owned solely by Teva / Sicor, (b) the entire right and title in all inventions, discoveries, improvements or other technology directed to the manufacture or use of the Device, and all processes relating thereto, whether or not patentable, and any patent applications or patents based thereon (the "Antares Inventions"), shall be owned solely by Antares; and (c) the entire right and title in all inventions, discoveries, improvements or other technology directed to the manufacture or use of the Product, and all processes relating thereto, whether or not patentable, and any patent applications or patents based thereon (the "Joint Inventions"), will be determined by the laws of inventorship under U.S. patent law.
- 9.1.1 Securing Patent Rights. Each Party agrees to cooperate with the other in completing any patent applications and in execution and delivery of any related instruments required to secure, assign, convey or transfer the patent rights in accordance with Section 9.1 hereof. Each Party shall promptly disclose to the other any Inventions made by employees or others acting on behalf of such Party. Teva / Sicor and Antares each hereby represents that all employees and other Persons acting on its behalf in performing its obligations under the Agreement shall be obligated under a binding written agreement to assign to it, or as it shall direct, all intellectual property made or developed by such employees or other Persons. Each Party shall be responsible for and shall bear all applicable costs associated with the filing, prosecution and maintenance of their respective patent rights and the Parties shall equally share in the costs directed to patent rights for Joint Inventions with one of the Parties, upon mutual agreement, taking the lead responsibility for preparing, filing and prosecuting the application for securing patent rights for the Joint Invention.
- 9.2 <u>Enforcement</u>. Antares and Teva / Sicor shall promptly notify the other in writing of any alleged or threatened infringement of the patent rights of which they become aware. Each Party shall have the right to enforce any of their respective patent rights hereunder. If either Party elects not to proceed with enforcement activity within (i) ninety (90) days following the notice of alleged infringement or (ii) ten (10) days before any applicable time limit set forth in

the appropriate laws and regulations for the filing of such actions, whichever comes first, then the Party owning the patent rights agrees to grant the other Party, at such other Party's sole expense, the right to enforce the infringement rights on such Party's behalf. In the event a Party brings an infringement action, the other Party shall cooperate fully, including, if required to bring such action, the furnishing of a power of attorney. Neither Party shall have the right to settle any patent infringement litigation under this Section 9.2 in a manner that diminishes the rights or interests of the other Party without the express written consent of such other Party. The costs of any litigation commenced pursuant to this Section 9.2, including attorneys' fees and expenses, shall be borne by the Party commencing such litigation, unless the Parties agree to a different cost sharing arrangement in any particular matter. Any recovery realized by a Party commencing such litigation shall be retained by such Party.

Except as otherwise agreed to by the Parties as part of a cost sharing arrangement, any recovery realized or liability created as a result of such joint litigation shall be shared equally by the Parties, after deduction of the costs of litigation incurred by the Party commencing such litigation (unless they agree beforehand to a different sharing of such recovery).

9.3 Third Party Infringement Actions. If Antares or Teva / Sicor or their respective customers is sued by a Third Party for infringement of a patent because of the manufacture, use or sale of the Product, each Party promptly shall notify the other Party in writing of the institution of such suit.

### ARTICLE 10 TERM AND TERMINATION

Agreement shall commence from the date of this Agreement and continue in full force and effect until the later of (a) ten (10) years from the date of this Agreement, or (b) the expiration of the last to expire Antares patent with valid claims covering the Device or the Product that is filed no later than 12 months after FDA approval of the Product. The term of this Agreement shall be automatically renewed for successive periods of two (2) years each, unless either Party notifies the other not less than twelve (12) months prior to the end of the initial term or any renewal term that this Agreement shall terminate at the end of such initial term or renewal term.

#### 10.2 Termination.

- 10.2.1 Termination by Either Party. Either Party may terminate this Agreement:
- (a) upon or after the material breach of this Agreement by the other Party if that Party has not cured such breach within sixty (60) days after receipt of written notice thereof (or fifteen (15) days in the case of nonpayment) by the nonbreaching Party; provided, however, that each Party shall have such longer period as may be needed to cure such breach, other than for nonpayment, provided that it has promptly commenced and continues diligently to pursue such cure;

- (b) subject to applicable bankruptcy laws, if the other Party voluntarily commences any action or seeks any relief regarding its liquidation, reorganization, dissolution or similar act or under any bankruptcy, insolvency or similar law; or
- (c) subject to applicable bankruptcy laws, if a proceeding is commenced or an order, judgment or decree is entered seeking the liquidation, reorganization, dissolution or similar act or any other relief under any bankruptcy, insolvency or similar law against the other Party, without its consent, which continues undismissed or unstayed for a period of sixty (60) days.
- 10.2.2 Termination by Teva / Sicor. Teva / Sicor may terminate the Agreement on (a) sixty (60) days' written notice (i) if Antares has not or cannot file and maintain an MAF, or an alternative regulatory submission, acceptable to FDA, (ii) if Antares cannot produce a Device meeting the specifications mutually agreed by the Parties in quantities and at times requested by Teva / Sicor according to order lead times agreed by the Parties, (iii) if Antares cannot provide the Device to Teva / Sicor at the pricing stated in section 5.3 above or the parties cannot agree to new pricing under the procedures described in section 5.5 above, (iv) if Antares undergoes a Change of Control that results in the control of Antares, or its Affiliates, by a Third Party that competes directly with Teva Pharmaceutical Industries, Ltd, or any of its Affiliates, including, but not limited to Teva Pharmaceuticals USA, and Teva / Sicor, or (b) one hundred eighty (180) days notice in the event that Teva / Sicor determines, in its sole discretion, that the sale of the Product is no longer commercially viable.
- 10.2.3 Termination by Antares. Antares may, at its option, terminate this Agreement, or convert the license granted in section 3.1 hereof into a non-exclusive license and terminate the provisions of section 3.3 hereof on sixty (60) days' written notice if Teva / Sicor (a) has not received regulatory approval to market the Product by the later of (i) May 28, 2009 or (ii) within ninety (90) days of the earliest date that Teva / Sicor could market the Product pursuant to a Paragraph III Certification; or (b) has not launched the Product within three (3) months of receiving regulatory approval to market the Product. Antares may terminate the Agreement immediately should Teva / Sicor cease to sell any Product provided that Teva / Sicor's selling efforts were not stopped as a result of an order or directive from FDA related to the Device or by Antares' inability to supply the Device. In addition, Antares may terminate the Agreement on twelve (12) months' written notice if (x) Antares' fully burdened cost of goods sold (determined in accordance with United States generally accepted accounting principles, consistently applied) exceeds the pricing stated in section 5.3 or 5.4 (as applicable) above, and (v) the parties cannot agree to new pricing-under the procedures described in Section 5.5 above, or (z) Teva / Sicor's purchases (including purchases from Antares by Teva / Sicor's sublicensees) of the Device from Antares fall below 250,000 units for any twelve (12) month period beginning six (6) months after the launch of the first Product.
- 10.3 <u>Effects of Termination</u>. Except as otherwise provided in this Agreement, upon termination of this Agreement:
- 10.3.1 All rights, privileges and licenses granted by Antares to Teva / Sicor shall terminate and revert to Antares, and Teva / Sicor shall not thereafter make any use whatsoever of any Confidential Information, Antares Patent Rights or Licensed Technology, provided,

however, if Teva / Sicor terminates this Agreement pursuant to Sections 10.2.1(b) or (c), this Agreement may continue in accordance with applicable bankruptcy laws.

- 10.3.2 In the event Antares terminates this Agreement pursuant to Section 10.2.1 or 10.2.3, or Teva / Sicor terminates this Agreement pursuant to Section 10.2.2(b), Teva / Sicor shall make a payment to Antares in an amount equal to Antares' undepreciated capital expenses that were incurred after the Effective Date and that were approved by Teva/Sicor, such approval not to be unreasonably withheld, and were directly related to the manufacture of the Device for Teva / Sicor, less any up-front payments and milestone payments, excluding payments made in exchange for stock, received by Antares and not repaid to Teva / Sicor. Notwithstanding the foregoing, in no case shall such a payment exceed five hundred thousands dollars (\$500,000).
- 10.3.3 In the event Teva / Sicor terminates this Agreement pursuant to Section 10.2.1 or Sections 10.2.2(a) or (b), Antares shall promptly execute whatever documents are necessary and take whatever steps are necessary, free of charge except for out-of-pocket expense, to provide Teva / Sicor with access to Antares' MAF(s) and a license to the Antares Patent Rights and Know How which are consistent with the rights provided under the license set forth in Section 3.1 hereof and are necessary to allow Teva / Sicor to sell, offer for sale, import and distribute the Product in the Field in the Territory for the remainder of the then current term.
- 10.3.4 In the event that Teva/Sicor terminates this Agreement pursuant to Section 10.2.2(b) hereof between January 1, 2008 and February 6, 2009, Teva/Sicor shall pay Antares a termination fee of \$500,000.
- 10.3.5 Subject to subparagraph 10.3.6 below, Teva / Sicor and its Affiliates shall cease all manufacturing, sales and marketing of the Product, provided that Teva / Sicor shall have the right to sell Product in its inventory or Product in distribution channels for a period not to exceed six (6) months, provided that Antares shall continue to receive any royalty payable thereon as provided in this Agreement.
- 10.3.6 Unless this Agreement is terminated by Teva / Sicor pursuant to Section 10.2.1 hereof. Antares, at its election, shall:
- (a) grant Teva / Sicor sufficient time, but no longer than six (6) months, to sell off its existing stocks of the Product, provided that Antares shall continue to receive any royalty payable thereon as provided in this Agreement; or
- (b) purchase from Teva / Sicor at Teva / Sicor's cost, any stock of the Device held by Teva / Sicor.

#### 10.4 Survival.

10.4.1 Termination of this Agreement for any reason shall not release either Party hereto from any liability which, at the time of such termination, has already accrued to the other Party.

- 10.4.2 Notwithstanding anything herein to the contrary, either Party's Legal Division shall be entitled to retain one archival copy of all materials covered by Article 7 hereof, for the sole purpose of determining such Party's ongoing confidentiality obligations.
  - 10.4.3 Termination shall be the sole remedy under Section 10.2.2 hereof.
- 10.4.4 Except as otherwise provided in Paragraph 10.4.3 hereof, termination shall not be the sole remedy under this Agreement and whether or not termination is effected all other remedies will remain available.
- 10.4.5 Articles 1, 7 (including specifically the deductions used in calculating "Net Sales" pursuant to section 1.16 hereof), 8, 9, 11, 12, this Section 10.4 and any obligations of a Party to make payments to the other Party hereunder accruing prior to the termination of the Agreement, shall survive the expiration and termination of this Agreement.

## ARTICLE 11 INDEMNITY

- 11.1 Indemnification by Teva / Sicor. Teva / Sicor agrees to indemnify, defend and hold harmless Antares, its Affiliates and their respective employees against any and all Third Party claims, losses, damages and liabilities, including reasonable attorney's fees, incurred by any of them arising out of any breach of any obligation by Teva / Sicor hereunder, any misrepresentation by Teva / Sicor hereunder, any negligent or intentionally wrongful act or omission by Teva / Sicor in connection with the performance of this Agreement by Teva / Sicor or the manufacture or sale of Product hereunder, or any claim that the method of production, sale or use of the Product (other than methods used under the Licensed Technology to make Device) infringes one or more claims of a patent or any trade secret or other intellectual property right.
- 11.2 <u>Indemnification by Antares</u>. Antares agrees to indemnify, defend and hold harmless Teva / Sicor, its Affiliates, and its employees against any and all Third Party claims, losses, damages and liabilities, including reasonable attorney's fees, incurred by any of them arising out of any claim that the Device infringes one or more claims of a patent or any trade secret or other intellectual property right, and any claim based on any misrepresentation by Antares hereunder, any negligent or intentionally wrongful act or omission by Antares in connection with the performance of this Agreement by Antares.
- 11.3 Procedure. If Teva / Sicor, its Affiliates or their respective employees, or Antares, its Affiliates or their respective employees (in each case an "Indemnified Party") receive any written claim which such Indemnified Party believes is the subject of indemnity hereunder by Teva / Sicor or Antares as the case may be (in each case an "Indemnifying Party"), the Indemnified Party shall, as soon as reasonably practicable after forming such belief, give notice thereof to the Indemnifying Party; provided, that the failure to give timely notice to the Indemnifying Party as contemplated hereby shall not release the Indemnifying Party from any liability to the Indemnified Party unless the Indemnifying Party demonstrates that the defense of such claim is prejudiced by such failure. In case any such proceeding shall be brought against any Indemnified Party and it shall notify the Indemnifying Party of the commencement thereof, the Indemnifying Party shall be entitled to participate therein and, to the extent that it shall wish

to assume the defense thereof, with counsel reasonably satisfactory to such Indemnified Party and shall pay as incurred the fees and disbursements of such counsel related to such proceeding. In any such proceeding, any Indemnified Party shall have the right to retain its own counsel at its own expense. Notwithstanding the foregoing, the Indemnifying Party shall pay as incurred (or within 30 days of presentation) the reasonable fees and expenses of the counsel retained by the Indemnified Party in the event (i) the Indemnifying Party and the Indemnified Party shall have mutually agreed to the retention of such counsel, (ii) the named parties to any such proceeding (including any impleaded parties) include both the Indemnifying Party and the Indemnified Party and representation of both parties by the same counsel would be inappropriate due to actual or potential differing interests between them or (iii) the Indemnifying Party shall have failed to assume the defense and employ counsel reasonably acceptable to the Indemnified Party within a reasonable period of time after notice of commencement of the action. It is understood that the Indemnifying Party shall not, in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the reasonable fees and expenses of more than one separate law firm for all such indemnified parties. Such firm shall be designated in writing by Teva / Sicor in the case of parties indemnified pursuant to Section 11.1 and by Antares in the case of parties indemnified pursuant to Section 11.2. The Indemnifying Party shall not be liable for any settlement of any proceeding effected without its written consent but if settled with such consent or if there be a final judgment for the plaintiff, the Indemnifying Party agrees to indemnify the Indemnified Party from and against any loss or liability by reason of such settlement or judgment. In addition, the Indemnifying Party will not, without the prior written consent of the Indemnified Party, settle or compromise or consent to the entry of any judgment in any pending or threatened claim, action or proceeding of which indemnification may be sought hereunder (whether or not any Indemnified Party is an actual or potential party to such claim, action or proceeding) unless such settlement, compromise or consent includes an unconditional release of each Indemnified Party from all liability arising out of such claim, action or proceeding.

- 11.4 <u>Insurance</u>. Each Party shall carry comprehensive general liability insurance, including product liability insurance against claims for bodily injury or property damage in an amount of not less than \$2,000,000 per occurrence and \$2,000,000 in the aggregate. Such policy shall be endorsed to include the following: the policies shall provide for thirty (30) days' notice to the other Party of cancellation or material change in the coverage before such cancellation or change takes effect. Each Party shall carry the insurance coverage set forth herein during the term of this Agreement and for two (2) years following termination of this Agreement.
- 11.5 <u>Limitation of Liability</u>. In no event shall either Party be liable to the other for any consequential, incidental, special, punitive, or exemplary damages (including but not limited to loss of profits or revenues or other indirect damages), whether a claim for any such liability or damage is based upon a breach of contract, breach of warranty, fulfillment of warranty, negligence, strict liability, misrepresentation or any other theories of liability, even if the Party has been apprised of the possibility or likelihood of such damages occurring.

### ARTICLE 12 MISCELLANEOUS

12.1 <u>Notices</u>. Any consent, notice or report required or permitted to be given or made under this Agreement by one of the Parties to the other shall be in writing, mailed via certified

mail, return receipt requested, courier or facsimile transmission, addressed to such other Party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the addressor and (except as otherwise provided in this Agreement) shall be effective upon receipt by the addressee or five (5) business days after dispatch.

If to Teva / Sicor: SICOR Pharmaceuticals, Inc.

19 Hughes

Irvine, California 92618

Attention: Senior Vice President and General Manager

with a copy to: Teva North America

425 Privet Road Horsham, PA 19044

Attention: Senior Vice President and General Counsel

If to Antares: Antares Pharma Inc.

707 Eagleview Boulevard, Suite 414

Exton, Pennsylvania 19341 Attention: President and CEO

- 12.2 Force Majeure. Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement (except the payment of money due under this Agreement) to the extent, and for so long as, such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including fire, floods, weather conditions, embargoes, war, acts of war (whether war be declared or not), vandalism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, acts of God or acts, omissions, delays in acting or prohibitions by any governmental authority. The Party so affected shall give prompt notice to the other Party of such cause, and shall take whatever steps are necessary to relieve the effect of such cause as rapidly as reasonably possible.
- 12.3 <u>Assignment</u>. Except as expressly provided hereunder, this Agreement may not be assigned or otherwise transferred, nor may any right or obligations hereunder be assigned or transferred by either Party without the consent of the other Party which may not be unreasonably withheld or delayed; provided, however, that either may, without such consent, assign this Agreement and its rights and obligations hereunder in connection with the transfer or sale of all or substantially all of its business, or in the event of its merger or consolidation or change in control or similar transaction. Any permitted assignee shall assume all obligations of its assignor under this Agreement.
- 12.4 <u>Bankruptcy</u>. If Antares files a petition in bankruptcy, or enters into an arrangement with its creditors, or applies for or consents to the appointment of a receiver or trustee or makes an assignment for the benefit of creditors, or suffers or permits the entry of an order adjudicating it to be bankrupt or insolvent, all rights and licenses granted pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of 11 U.S.C. §101 et seq. (the "Bankruptcy Code"), licenses of rights to "intellectual property" as such term is defined under Section 101(35A) of the Bankruptcy Code. The Parties agree that Teva / Sicor, as

a licensee of such rights under this Agreement, subject to Teva / Sicor's compliance with its obligations under this Agreement, shall retain and may fully exercise all of its rights (including, without limitation, any right to enforce any exclusivity provision of this Agreement, including any embodiment of such intellectual property), remedies and elections under the Bankruptcy Code.

- 12.5 Severability. Each Party hereby acknowledges that it does not intend to violate any public policy, statutory or common laws, rules, regulations, treaty or decision of any government agency or executive body thereof of any country or community or association of countries. Should one or more provisions of this Agreement be or become invalid, the Parties shall substitute, by mutual consent, valid provisions for such invalid provisions which valid provisions in their economic effect are sufficiently similar to the invalid provisions that it can be reasonably assumed that the Parties would have entered into this Agreement with such provisions. In case such provisions cannot be agreed upon, the invalidity of one or several provisions of this Agreement shall not affect the validity of this Agreement as a whole, unless the invalid provisions are of such essential importance to this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without the invalid provisions.
- 12.6 <u>U.S. Export Laws and Regulations</u>. Each Party hereby acknowledges that the marketing rights and information disclosure requirements of this Agreement are subject to the laws and regulations of the United States relating to the export of products and technical information. Without limitation, each Party shall comply with all such laws and regulations. Each Party will comply with U.S. and international laws and regulations in connection with their activities required or permitted under this Agreement including manufacturing, distribution, marketing and labeling of Products.
- 12.7 <u>Entire Agreement</u>. The Agreement contains the entire understanding of the Parties with respect to the subject matter hereof. All express or implied agreements and understandings, either oral or written, heretofore made are expressly superseded by this Agreement. The Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by both Parties.
- 12.8 <u>Headings</u>. The captions to the several Articles and Sections hereof are not a part of this Agreement, but are merely guides or labels to assist in locating and reading the several Articles and Sections hereof.
- 12.9 <u>Independent Contractors</u>. It is expressly agreed that Teva / Sicor and Antares shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither Teva / Sicor nor Antares shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior consent of the Party to be bound so.
- 12.10 Amendment and Waiver. This Agreement may be amended, modified, superseded or cancelled and any of the terms waived, only by a written instrument executed by each Party, or in the case of a waiver, by the Parties or Party waiving compliance. The waiver by either Party of any right hereunder or the failure to perform or of a breach by the other Party

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shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.

- 12.11 <u>Payments</u>. All payments due to a Party under this Agreement shall be made in U.S. Dollars and be made by wire transfer to such Party's account in the depository designated from time to time by such Party.
- 12.12 No Third Party Beneficiaries. No Third Party including any employee of any Party to this Agreement, shall have or acquire any rights by reason of this Agreement. Nothing contained in this Agreement shall be deemed to constitute the Parties partners with each other or any Third Party.
- 12.13 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware.
- 12.14 <u>Counterparts</u>. The Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Signatures may be transmitted via facsimile, thereby constituting the valid signature and delivery of this Agreement, provided original copies are transmitted within forty-eight (48) hours to each Party after signature thereto.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first set forth above.

SICOR PHARMACEUTICALS, INC.
By /s/ Mark Durand
Title CFO SVP
ANTARES PHARMA INC.
By /s/ Jack E. Stover
Title President and CEO