# SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

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FORM 8-K CURRENT REPORT Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

MAY 11, 1998

Date of Report (Date of earliest event reported)

A <sup>-</sup>	TLANTIC PHARMACEUTICALS, INC.	
(Exact name	of registrant as specified i	n charter)
DELAWARE	0-27282	36-3898269
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)
1017 MAIN CAMPUS DRIVE, S	SUITE 3900, RALEIGH, NORTH CA	ROLINA 27606
(Address of pr	incipal executive offices)	(Zip Code)
Registrant's telephone number	, including area code (919	) 513-7020
	N/A	
(Former name or fo	ormer address, if changed sind	ce last report.)

#### Item 5. Other Events.

On May 14, 1998, the Registrant's majority-owned subsidiary, Optex Ophthalmologics, Inc. ("Optex"), entered into a worldwide licensing agreement with Bausch & Lomb Surgical (comprised of Chiron Vision Corporation and Storz Instrument Company), a division of Bausch & Lomb Incorporated, to complete the development of Catarex-TM-, a cataract-removal technology invented by Optex. Under the terms of the agreement, Bausch & Lomb Surgical and Optex intend to jointly complete the final design and development of the Catarex system. Bausch & Lomb Surgical will assume responsibility for commercializing Catarex globally. Optex received up-front payments and is to receive certain milestone payments from Bausch & Lomb Surgical. In addition, Bausch & Lomb has committed to pay ongoing royalties on sales of Catarex products.

On May 11, 1998, the Registrant adjourned its regularly-scheduled annual meeting of shareholders, at which no shareholder action was taken. The meeting is scheduled to re-convene on June 15, 1998.

#### Item 7. Exhibits.

A copy of the Development & License Agreement, dated May 14, 1998, by and between Optex Ophthalmologics, Inc. and Bausch & Lomb Surgical (comprised of Chiron Vision Corporation and Storz Instrument Company), a division of Bausch & Lomb Incorporated, is attached hereto as Exhibit 99.1 and incorporated herein by reference.

## **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

(Registrant)

Date: May 22, 1998 By /s/ Shimshon Mizrachi

Name: Shimshon Mizrachi Title: Chief Financial Officer

# INDEX TO EXHIBITS

Exhibit No.	Description 	Page
99.1	Development & License Agreement, dated May 14, 1998, by and between Optex Ophthalmologics, Inc. and Bausch & Lomb Surgical (comprised of Chiron Vision Corporation and Storz Instrument Company), a division of Bausch & Lomb Incorporated.	

#### DEVELOPMENT & LICENSE AGREEMENT

THIS DEVELOPMENT AND LICENSE AGREEMENT is entered into this 14th day of May 1998, (the "EFFECTIVE DATE") by and between Optex Ophthalmologics, Inc. ("OPTEX") and Bausch & Lomb Incorporated's surgical unit (comprised of Storz Instrument Company and Chiron Vision Corporation) doing business as Bausch & Lomb Surgical ("B&L" and together, the "PARTIES").

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WHEREAS, Optex has developed a proprietary surgical instrument system designed to improve the removal of human cataracts, which instrument is generally referred to as "Catarex-TM-"; and

WHEREAS, B&L desires to acquire certain rights to make, use and sell Catarex for use in human ophthalmic indications on a worldwide basis; and

WHEREAS, the Parties desire hereby to set forth the terms and conditions under which Optex will license to B&L and B&L will complete the commercial development, clinical testing, manufacturing and commercial sale of Catarex on a worldwide basis.

NOW, THEREFORE, in consideration of the promises, mutual covenants and agreements set forth in this Agreement, the Parties agree as follows:

#### DEFINITIONS

- 1.1 "AFFILIATE" of a specified Person means any other Person which directly or indirectly, is in control of, is controlled by or is under common control with such specified Person. For purposes of this definition "control" of a Person means beneficial ownership of securities or other interests in such Person constituting fifty percent (50%) (or, if lower, any applicable maximum foreign ownership percentage allowed under the laws of any jurisdiction) or more of the Voting Power in such Person. "Beneficial ownership" shall be determined in compliance with Rule 13d-3 of the Securities Exchange Act of 1934.
- 1.2 "B&L FIELD" means all applications of Catarex Products for human ophthalmic surgery.
- 1.3 "B&L INVENTIONS" means all inventions relating to Catarex Products in the Field made or discovered solely by employees or agents of B&L in the course of the conduct of the development of Catarex Products under this Agreement.

counterparts claiming any B&L Inventions and all patents issued pursuant to any such patent applications, and all substitutions, divisionals, reissues, renewals, continuations, continuations-in-part, or extensions thereof.

- 1.5 "CATAREX COMBINATION PRODUCT" means a Catarex Consumable offered for commercial sale in combination with other consumables that are not used in the operation of the Catarex Unit, the combination of which would be part of a package or kit. Examples of other consumables are sponges, drapes, and disposable knives.
- 1.6 "CATAREX CONSUMABLES" means those single use disposables or reusable components used in the operation of the Catarex Units. Examples are: (1) the Catarex handpiece and tip, (2) the device connecting the tip to the console, (3) a drive unit, (4) the tubes and collection container for collecting fluids generated by the Catarex probe, and (5) the capsulorhexis probe.
- 1.7 "CATAREX UNIT" means the Catarex rotary vortex device including the Catarex Plugin, drive unit, a collection system, a control system and, and related capsulorhexis probe, each as further described in Exhibit C attached hereto, including any improvements thereof during the term of this Agreement.
- 1.8 "CATAREX/MILLENNIUM UNIT" means a Millennium-TM- system, initially built with a Catarex Unit as a subunit assembly.
- 1.9 "CATAREX MODULE" means a Catarex Unit configured as a subunit assembly for use in an installed Millennium-TM- system.
- 1.10 "CATAREX PLUGIN" means the component portion of a Catarex Unit which is physically incorporated in the Catarex/Millennium Unit and which may include the drive unit and control system for a Catarex Unit.
- 1.11 "CATAREX PRODUCTS" means any product whose manufacture, use, importation, or sale would infringe Optex Patents, but including without limitation, the Catarex Unit, Catarex Combination Product, Catarex Consumables, Catarex Standalone Unit, Catarex/Millennium Unit, Catarex Modules, and Catarex Plugin, and any improvements thereto.
- 1.12 "CATAREX STANDALONE UNIT" means a Catarex Unit configured as a standalone product which may be used independent of a Millennium-TM- system.
  - 1.13 "CLINICAL DEMONSTRATION" has the meaning given in Exhibit A.
- 1.14 "DEVELOPMENT" means both preclinical and clinical research on, engineering development work on, manufacturing scale-up of, and obtaining regulatory approvals for the sale of Catarex Products for any indication within the B&L Field.
- 1.15 "FIELD" means all applications of Catarex Products for ophthalmic surgery.

- 1.16 "FIRST COMMERCIAL USE" means the first commercial sale of a Catarex Product in a Key Market.
- 1.17 "JOINT INVENTIONS" means all inventions relating to Catarex Products in the Field which are made or jointly discovered by employees or agents of B&L and Optex.
- 1.18 "JOINT REVIEW COMMITTEE" means the Committee established pursuant to Section 4.2 to review the development and commercialization of the Catarex Products.
- 1.19 "KEY MARKETS" means the United States, the United Kingdom, Germany, France, Spain, Italy, Canada, Australia, and Japan.
- 1.20 "KNOW-HOW" means all technology, inventions, methods, formulas, trade secrets, technical data, preclinical and clinical data, toxicological and any other information or experience owned, controlled or in the possession of Optex as of the Effective Date relating to or useful in connection with the development, manufacture, use or sale of Catarex Products in the B&L Field, as well as any improvements or modifications to such Know-how developed by Optex in the B&L Field during the term of this Agreement.
- 1.21 "LIQUID POLYMER LENS" means a synthetic and injectable liquid or gellular lens that substitutes for the traditional intraocular lens, provides for accommodation, and is used to refill the functionally intact human lens capsule following cataract removal using a Catarex Product.
- 1.22 "MILLENNIUM-TM- SYSTEM" means the modular cataract removal system currently marketed under the Millennium-TM- trademark and any improvements or new versions thereof or substitutions therefor.
- 1.23 "NET SALES" means the gross sales price invoiced by B&L and its Affiliates or sublicensees to unaffiliated third parties for the sale or other transfer for value of Catarex Products, less the following: (i) customary, usual and reasonable trade or quantity discounts actually taken by the customer; (ii) sales, use, value-added, or excise taxes, imposed and paid directly with respect to the sale, and included within the invoice price; and (iii) actual refunds for customer returns, and (iv) charges for freight and insurance billed to the customer.
- 1.24 "OPTEX CRITICAL TECHNOLOGY" means the following portion of the Catarex Products: the tip, as shown in Exhibit D(i), containing a rotating lens-reducing head, as shown in Exhibit D(ii), which is used by insertion of such tip into the lens capsule of a cataract-affected human eye such that the subsequent rotation of such lens-reducing head, without concurrent ultrasonic vibration of the tip, induces a flow pattern within the lens capsule, which (a) causes the cataract-affected lens to be drawn into contact with such rotating lens-reducing head without substantial axial manipulation of the probe and (b) results in reduction of the cataract-affected lens to a flowable consistency.
- 1.25 "OPTEX FIELD" means all applications of Catarex Products for other than human  $\,$

ophthalmic surgery, e.g. for commercial applications in animals.

- 1.26 "OPTEX PATENTS" means all United States patent applications and their foreign counterparts owned or controlled by Optex and its Affiliates claiming any Catarex Products including, without limitation, the patents and patent applications listed in Exhibit B attached hereto, and all patents issued pursuant to any such patent applications, and all substitutions, divisionals, reissues, renewals, continuations, continuations-in-part, or extensions thereof. Optex Patents shall include patents and patent applications based upon Optex Inventions and Joint Inventions. The Parties shall reasonably agree to amend Exhibit B from time to time to reflect material new patent properties.
- 1.27 "OPTEX INVENTIONS" means all inventions relating to Catarex Products in the Field made or discovered solely by employees or agents of Optex in the course of the conduct of the development of Catarex Products under this Agreement.
- 1.28 "PERSON" means an individual, partnership, limited liability company, business association, trust, corporation or other entity, whether DEJURE or DEFACTO.
  - 1.29 "STATUS REPORT" has the meaning given in Section 4.2.
- 1.30 "VOTING POWER" with respect to a specified Person means (i) if the Person is a corporation, the right to vote in the election of directors of the corporation in the ordinary course, (ii) if the Person is a trust, the right to appoint trustees of the trust, (iii) if the Person is a limited liability company, the right to name managing members of the limited liability company and (iv) if the Person is any other type of entity, any concepts similar to the foregoing relating to the power to control the business and affairs of such Person.

#### 2. GRANT

- 2.1 LICENSE GRANT. Subject to the terms and conditions of this Agreement, Optex grants to B&L an exclusive, worldwide, license, with the right to grant sublicenses, under Optex Patents and Know-how to make, have made, use, import, offer for sale and sell the Catarex Products in the B&L Field. The Parties acknowledge and agree that no rights outside the B&L Field are granted herein to B&L by Optex, including, without limitation, any rights under Optex Patents or Optex Know-how within the Optex Field.
- 2.2 SUBLICENSE RIGHTS. B&L shall have the right to sublicense the license granted in Section 2.1 subject to the prior written approval of Optex, which approval shall not be unreasonably withheld or delayed, so long as each sublicensee agrees to be bound by all of the terms and conditions of this Agreement, except that no consent of Optex shall be required for sublicenses to Affiliates of B&L. Further, B&L shall have the right to appoint the distributor(s) of its choice pursuant to its normal distribution channels, without the approval of Optex provided such distributor agrees to be bound by all of the terms and conditions of this Agreement which are relevant to the activities of such distributor.

#### 3. FEES AND ROYALTIES

- 3.1 GENERALLY. As consideration for the exclusive license granted to B&L under Section 2.1 hereof, B&L shall pay the following fees and royalties.
- 3.1.1 FEES. B&L shall pay Optex an aggregate of Nine Million Five Hundred Thousand Dollars (\$9,500,000) in fees payable as indicated in this Section 3.1.1. All payments due to Optex under this Section 3.1.1 shall be paid within ten (10) days following the occurrence of Milestones I, II, III, or IV, respectively. Milestone III shall be creditable in full against royalties payable under Sections 3.1.3 and 3.1.4 at a rate of thirty percent (30%) of the royalties as due and payable thereunder.
- 3.1.1.1 On the Effective Date of this Agreement B&L shall pay Optex a non-refundable license fee of 2,500,000 ("MILESTONE I").
- 3.1.1.2 Upon a determination by B&L that the Clinical Demonstration has been successfully completed, but in no event later than First Commercial Use), B&L shall pay Optex a fee of \$4,000,000 ("MILESTONE II").
- 3.1.1.3 Upon the later of regulatory approval to market a Catarex Product in the United States by the United States Food & Drug Administration ("REGULATORY APPROVAL") or, upon a determination by B&L that the Clinical Demonstration has been successfully completed (if B&L has committed to complete such Clinical Demonstration, but in no event later than First Commercial Use, B&L shall pay Optex a fee of \$2,000,000 (MILESTONE III").
- 3.1.1.4 Upon receipt of regulatory approval to market a Catarex Product in Japan by the Japanese Kosheisho ("JAPANESE REGULATORY APPROVAL"), B&L shall pay Optex a fee of \$1,000,000 ("MILESTONE IV").
- 3.1.2 MINIMUM CATAREX PRODUCT ROYALTIES. B&L shall pay Optex minimum Catarex Product royalties of the following amounts in the three year period immediately following First Commercial Use:

First twelve months \$ 90,000 Second twelve months \$350,000 Third twelve months \$750,000

- If, during the periods set forth above, actual Catarex Product royalties to Optex are less than the required minimums amounts set forth above, then B&L shall have sixty (60) days from the date of notice by Optex to pay the shortfall to maintain exclusivity of the license. If B&L fails to make any such payment within sixty (60) days of the notice by Optex then the license shall at Optex's option immediately become non-exclusive to B&L.
- 3.1.3 CATAREX PRODUCT ROYALTIES. During the term of this Agreement, B&L shall pay Optex an earned royalty of seven percent (7%) of Net Sales of Catarex Products. For the purpose of royalty calculations, the Net Sales price of the Catarex/Millennium Unit shall be deemed to be \$25,000 for markets where B&L has direct sales and \$20,000 where B&L sells

through unaffiliated distributors. For purposes of determining the Net Sales of Catarex Consumables the Parties shall, on an annual basis in advance of the year for which prices are to apply, agree in good faith on the percentage of the Net Sales prices for Catarex Combination Products to be allocated to the Catarex Consumables included therein, which percentage(s) shall reflect an appropriate allocation of the Net Sales price of the Catarex Combination Product based upon the costs of and profit margins for each product item contained in a Catarex Combination Product.

- 3.1.4 ADDITIONAL LIQUID POLYMER LENS ROYALTY. B&L shall pay Optex an additional royalty of three percent (3%) on the product of (A) Net Sales of Catarex Consumables in Key Markets, times (B) the then fractional market share of Liquid Polymer Lenses in the United States intraocular lens market; which royalty shall be paid for any calendar quarter during which Liquid Polymer Lenses achieve a 10% market share of the United States intraocular lens market, as measured by published Deloitte & Touche (or similar third party surveys if unavailable) surveys of such market; UNLESS during such calendar quarter an alternative cataract removal system which enables the use of accommodating liquid polymer lens implantation has achieved greater than 10% market share of sales of cataract removal systems in the United States as measured by published surveys of such market. Should a published survey not be available to the Parties, market share shall be determined by other published and mutually agreeable market share data, or in the absence of such market share data then as reasonably determined by the Parties in good faith.
- 3.1.5 TIMING OF ROYALTY PAYMENTS. Within forty-five (45) days after the end of each calendar quarter, B&L, B&L Affiliates and/or B&L sublicensee(s) as the case may be, shall pay to Optex the royalty payment due for such quarter in U.S. dollars.
- 3.1.6 ROYALTY PAYMENT CONVERSION. For any sales made in currencies other than the U.S. dollar, such royalty shall be converted from the currency in which the sale was made into U.S. dollars at the exchange rate published in the WALL STREET JOURNAL for the last business day of the calendar quarter during which such sale occurs.
- 3.1.7 QUARTERLY ACCOUNTING. Together with the delivery of each such royalty payment, B&L, B&L Affiliates and/or B&L sublicensees, as the case may be, shall deliver to Optex a written accounting showing its computation of royalties due under this Agreement for such quarter. Such accounting shall set forth gross sales, Net Sales, an accounting of the calculation of Net Sales, the exchange rate applied, if any, and the total royalties due for the quarter in question.
- 3.1.8 LATE PAYMENTS. Any amount not paid when due under this Agreement shall bear interest at one and one-half percent (1.5%) per month, compounded monthly or, if less, the highest amount permissible under applicable law; PROVIDED, HOWEVER, that no such interest shall be payable with respect to any amounts subject to a BONA FIDE dispute between the Parties.
- 3.1.9 RECORDS. B&L shall keep full and accurate books and records reflecting the royalties on Net Sales and the data used in arriving at Net Sales and the amount of royalties

payable to Optex hereunder for no less than one year after the end of each such quarter. B&L shall permit Optex, once within any 12 month period, at Optex's expense, to have such books and records examined by independent certified public accountants retained by Optex and reasonably acceptable to B&L, during regular business hours upon reasonable advance notice, but not later than one year following the rendering of any such reports, accounting and payments. Such independent accountants shall keep confidential any information obtained during such examination. If such examination discloses a discrepancy of 5% or more in any amount due Optex under this Agreement, B&L shall reimburse Optex for the out-of-pocket cost of such examination, including without limitation any reasonable professional fees and expenses incurred by Optex.

#### 4. DEVELOPMENT

- 4.1 COLLABORATIVE DEVELOPMENT. The Parties acknowledge that all development of the Catarex Products, for all indications within the B&L Field shall be conducted in collaboration as provided in this Article 4. The role of each Party and the funding obligations of each Party with respect to such collaborative development shall be as set forth in this Article 4.
- 4.2 JOINT REVIEW COMMITTEE. Promptly following the execution of this Agreement, the Parties shall form a Joint Review Committee consisting of two (2) representatives from each Party, to update each other upon the respective development efforts for Catarex Products. While the Catarex Products are in development, the JRC will meet at least on a quarterly basis, alternating between Optex's offices and B&L's offices and will otherwise communicate regularly by all reasonable means. Thereafter, the JRC will meet at such times and places as may be agreed to by the Parties. A Party may change any of its appointments to the JRC at any time upon giving written notice to the other Party. At least one (1) week prior to any regularly scheduled meeting of the JRC, each Party shall provide the other Party with a report summarizing its efforts under this Agreement (the "STATUS REPORT").
- 4.3 RESPONSIBILITIES OF THE JRC. The JRC will be responsible for reviewing and commenting upon all aspects of the collaborative development of the Catarex Products in the Field. In particular, the JRC will monitor the development of Catarex Products, including the regulatory approval process.
- 4.4 RESPONSIBILITIES OF OPTEX; DEVELOPMENT PLAN AND BUDGET FOR OPTEX DEVELOPMENT WORK. Optex shall be responsible for the development of the tip of the Catarex Unit, and the portion of the Catarex Unit between the tip and Catarex Plugin. The development work to be conducted by Optex shall be governed by a specific and comprehensive development plan and budget (the "DEVELOPMENT PLAN AND BUDGET"), proposed by Optex and approved by B&L and consistent, to the maximum extent possible, with recommendations of the JRC. No development work by Optex under this Agreement shall be conducted other than pursuant to the Development Plan and Budget. The Development Plan and Budget shall outline fully the proposed work to be conducted by Optex and time-line for completion of the Optex duties, which are expected to include process development, manufacture of prototypes, quality assurance, manufacturing, and other key elements needed to obtain regulatory approval. The Development Plan and Budget shall be divided by Optex into up to ten discrete components. If at any time, Optex foresees that

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completion of its development responsibilities shall not be possible without one or more of such discrete budgetary components exceeding the budgeted amount therefor by more than ten percent (10%), Optex shall immediately notify B&L. Optex shall not exceed the budgeted amount of any such discrete component of the Development Plan and Budget without prior approval of B&L, which shall not be unreasonably withheld. To the extent that additional expenditures are reasonably required, B&L shall fund such additional expenditures; provided, however, that B&L shall have no funding obligations in excess of \$2,500,000.

- 4.5 RESPONSIBILITIES OF B&L. B&L shall be responsible for, and shall use all commercially reasonable efforts to do the following as expeditiously as possible and in accordance with the time lines set forth in Section 8.1.3:
- 4.5.1 develop all elements of Catarex Products other than those to be developed by Optex pursuant to Section 4.4;
- 4.5.2 obtain regulatory approval of Catarex Products in the United States and outside the United States; and
  - 4.5.3 manufacture and market the Catarex Products.
  - 4.6 ALLOCATION OF DEVELOPMENT EXPENSES.
- 4.6.1 B&L will bear one hundred percent (100%) of all development expenses for B&L's Responsibilities in Section 4.5.
- 4.6.2 Optex shall initially incur the development expenses as defined in the Development Plan and Budget for Optex's Responsibilities in Section 4.4; PROVIDED, HOWEVER, that B&L shall, on a quarterly basis, reimburse all such development expenses incurred by Optex consistent with the Development Plan and Budget, including, without limitation, labor, out-of-pocket expenses, professional services, materials, and capital expenses. Within thirty (30) days following the end of each calendar quarter, Optex will provide B&L with a report of its development expenses actually incurred during such quarter. Within thirty (30) days following the commencement of the calendar quarter, B&L shall pay to Optex the amount of reimbursement required in accordance with the approved Development Plan and Budget. Any funds received by Optex from NEI Phase II SBIR grant No. 2R44EY11673-02 will be credited against B&L's reimbursement obligations under this Section 4.6.2 to the extent permissible under the terms of such grant.
- 4.7 MAXIMUM DEVELOPMENT COSTS. If the aggregate amount of expense incurred by Optex pursuant to the Development Plan and Budget (and permitted increases thereto) shall exceed \$2,500,000, the Parties shall in good faith discuss whether any modifications to the terms of payment of Milestones II and/or III would be appropriate.
- 5. INTELLECTUAL PROPERTY
  - 5.1 JOINT INVENTIONS

5.1.1 Any Joint Invention shall be owned by and assigned to Optex. Optex hereby grants to B&L a permanent, exclusive license to practice any Joint Invention owned by Optex within the B&L Field on a royalty-free basis.

#### 5.2 PATENT PROSECUTION AND MAINTENANCE.

- 5.2.1 Optex has the sole right to continue prosecution and maintenance of the Optex Patents. Optex shall provide B&L with copies of all patent applications, prosecution documents, correspondence with government entities, and other information that B&L may request with respect to the Optex Patents and Optex shall keep B&L informed of patent prosecution and maintenance matters. B&L shall reimburse Optex for all documented expenses incurred after the Effective Date in connection with the filing, prosecution, and maintenance of the Optex Patents upon receipt of invoices for such expenses; PROVIDED, HOWEVER, that B&L shall not be obligated to reimburse Optex for any appellate proceedings commenced and pursued outside the United States Patent and Trademark Office or the equivalent administrative body in the other Key Markets unless Optex is successful in such proceedings. If Optex, prior or subsequent to filing any Optex Patents, elects not to file, prosecute, or maintain the Optex Patents or certain claims encompassed by such Optex Patents, Optex shall give B&L notice thereof within a reasonable period prior to allowing such Optex Patents or certain claims encompassed by such Optex Patents to lapse or become abandoned or unenforceable, and B&L shall thereafter have the right and option, at its sole expense, to prepare, file, prosecute and maintain such Optex Patents or certain claims encompassed by such Optex Patents in countries of its choice throughout the world. Such option shall be exercisable by B&L only within an option period of sixty (60) days of receipt of such notice.
- 5.2.2 Optex shall have the right, at its option, to prepare, file and prosecute any patent applications with respect to any Optex Inventions owned solely by Optex. In connection therewith, B&L agrees to cooperate with Optex, at Optex's expense, in the preparation and prosecution of all such patent applications and in the maintenance of any patents issued therefrom (together "Optex Invention Patents"). If Optex, prior or subsequent to filing any Invention Patents, elects not to file, prosecute, or maintain such Optex Invention Patents or certain claims encompassed by such Optex Invention Patents, Optex shall give B&L notice thereof within a reasonable period prior to allowing such Optex Invention Patents or certain claims encompassed by such Optex Invention Patents to lapse or become abandoned or unenforceable, and B&L shall thereafter have the right, at its sole expense, to prepare, file, prosecute and maintain such Optex Invention Patents or certain claims encompassed by such Optex Invention Patents in countries of its choice throughout the world. Such option shall be exercisable by B&L only within an option period of sixty (60) days of receipt of such notice.
- 5.2.3 The Parties shall mutually determine which Party shall file, prosecute and maintain patent applications with respect to inventions jointly owned by Optex and B&L (the "Filing Party"). B&L shall pay for all out-of-pocket costs of such patent filings and applications. Each Party shall have the right to review and comment on any joint patent application prior to its filing, and to consult with the Filing Party with respect to prosecution of such application. If the Filing Party, prior or subsequent to filing any such applications elects not to file, prosecute, or

maintain such applications or certain claims encompassed by such applications, the Filing Party shall give the other Party notice thereof within a reasonable period prior to allowing such patent applications or certain claims encompassed by such applications to lapse or become abandoned or unenforceable, and the other Party shall thereafter have the right, at its sole expense, to prepare, file, prosecute and maintain patents or certain claims encompassed by such applications in countries of its choice throughout the world. Such option shall be exercisable by the other Party only within an option period of sixty (60) days of receipt of such notice.

- 5.2.4 B&L shall have the right, at its option, to prepare, file, prosecute and maintain any B&L Patents. With respect to the B&L Patents, and in connection therewith, Optex agrees to cooperate with B&L in the preparation and prosecution of all such patent applications and in the maintenance of any patents issued. B&L shall provide Optex with copies of all patent applications, prosecution documents, correspondence with government entities, and other information that Optex may request with respect to the B&L Patents. B&L shall provide Optex with a quarterly report of the status of such patents as part of the Status Report. If B&L, prior or subsequent to filing B&L Patents, elects not to file, prosecute or maintain such B&L Patents or certain claims encompassed by such B&L Patents, B&L shall give Optex notice thereof within a reasonable period prior to allowing such B&L Patents or certain claims encompassed by such Patents to lapse or become abandoned or unenforceable, and Optex shall thereafter have the right, at its sole expense, to prepare, file prosecute and maintain such B&L Patents or certain claims encompassed by such B&L Patents in countries of its choice throughout the world. Such option shall be exercisable by Optex only within an option period of sixty (60) days of receipt of such notice.
- 5.2.5 B&L shall grant to Optex an option to a worldwide, royalty-bearing, nonexclusive license (including the right to grant sublicenses), under any B&L Inventions or B&L Patents to develop, have developed, make, have made, use, distribute for sale, offer for sale, sell, and import any product, and to practice any process, for all uses in the Optex Field. The other customary terms of such license shall be negotiated in good faith between the Parties. In addition, B&L shall provide Optex with reasonable access to such other information and B&L personnel as may be required in order for Optex to reasonable utilize the information licensed to it under this section.
- INFRINGEMENT OF THIRD PARTY PATENTS. If a third party asserts that a patent or other proprietary right owned by it is infringed by the manufacture, use, importation, offer for sale or sale of a Catarex Product, the Party against whom such a claim is asserted shall immediately provide the other Party notice of such claim and the related facts in reasonable detail. Optex shall have the first right, but not the obligation, to defend such action, and B&L shall cooperate in connection therewith, and shall have the right to be represented separately by counsel of its own choice, at its own expense. In the event a claim is asserted against B&L and Optex does not assume such defense, B&L shall have the right to defend such action. Optex shall cooperate in connection therewith, and shall have the right to be represented separately by counsel of its own choice, at its own expense. The entity (whether Optex or B&L) that controls the defense of a given claim with respect to the Catarex Product in the Field shall also have the right to control settlement of such claim; PROVIDED, HOWEVER, that no settlement shall be entered into without the consent of the other Party if such settlement would adversely affect the interests of such other

Party.

#### 5.4 THIRD PARTY INFRINGEMENT/MISAPPROPRIATION

- 5.4.1 If either Party becomes aware of any infringement of the Optex Patents or misappropriation of the Optex Know-How or the B&L Patents or misappropriation of the B&L Know-How by a third party in the Field, such Party shall promptly give notice thereof to the other Party and shall provide the other Party with any evidence or other information in its possession relating to such infringement or misappropriation. The Parties shall thereupon consult together as to the action to be taken.
- 5.4.2 Optex shall have the first right, but not the obligation, to commence legal proceedings against any infringer of any Optex Patent or misappropriation of Optex Know-How in the Field and in this case (subject to the provisions of the next two sentences) any damages recovered shall belong to Optex. In the event Optex commences such legal proceedings, B&L may join in such proceedings within sixty (60) days after its receipt of notice from Optex of the commencement of such proceedings if B&L agrees to pay an amount equal to fifty percent (50%) of the cost of such proceedings. In such event, any damages, settlement fees or other consideration for past infringement in the Field received as a result of such proceedings shall be shared by Optex and B&L equally. If Optex is not willing to undertake legal proceedings against the infringement or misappropriation in the B&L Field, B&L may at its own cost and expense in its own name commence such legal proceedings and in such case any damages recovered shall first be used to repay B&L its out-of-pocket costs incurred in bringing such action. Any amounts remaining shall be shared in the same proportion as if the sales represented by such amounts were Net Sales accruing during the year in which such recovery was obtained, as set forth in Section [ ]. Further, in such event, and subject to Optex's right of approval, B&L shall be free to settle such disputes, and Optex shall cooperate with B&L as reasonably requested by B&L.

#### 6. SUBLICENSE

B&L shall have the right, at its discretion, to sublicense the Catarex technology; PROVIDED, that the sales by any such sub-licensee shall constitute Net Sales hereunder for which royalties are payable.

#### 7. PRE-MARKET APPROVAL

If the FDA requires a pre-market approval ("PMA") of the Catarex Products, then the Parties agree that they shall meet in good faith to discuss whether any modifications to Milestones II and/or III are appropriate in order to reflect the incremental regulatory expenses associated with obtaining such pre-market approval.

#### 8. TERM AND TERMINATION

8.1 TERMINATION. This Agreement shall remain in full force and effect from the Effective Date until the expiration of the last to expire United States Optex Patent on Exhibit B (upon such expiration, B&L shall be granted a fully paid nonexclusive license to Know-how and

other Optex Patents), unless earlier terminated as follows:

- 8.1.1 By mutual consent of Optex and B&L;
- 8.1.2 By B&L at any time upon six (6) months written notice;

8.1.3 By Optex, if (i) Optex becomes insecure with respect to B&L's diligent pursuit and timely achievement of the tasks set forth in the timetable below, (ii) Optex requests reasonable assurances from B&L as to such matters, (iii) B&L fails to provide such reasonable assurances and Optex notifies B&L of such failure, and (iv) B&L shall not have cured the situation within thirty (30) days of the notification provided for under phrase (iii) or commenced a cure and diligently pursued such cure if it is reasonably likely to eliminate Optex's insecurity;

## MONTHS BEYOND COMPLETION OF HANDPIECE AND PROBE DESIGN

	510(K) ONLY	510(K) WITH CLINICALS
Module Design	1	1
Software Design	1	1
Sterility Validation	4 1/2	4 1/2
Pilot Production	8 1/2	8 1/2
510(k) Approval	2	
IDE Approval		11 1/2
Clinical Demonstration	14 1/2	19 1/2
Clinical Approval		19 1/2
Design Transfer/Order Parts	18 1/2	23 1/2
Production	18 1/2	23 1/2
Production Launch	18 1/2	23 1/2

- 8.1.4 By either Party, if B&L has declared the Clinical Demonstration to be a "complete failure"; and
- 8.1.5 By B&L, if B&L has declared the Clinical Demonstration to be a "partial success"; PROVIDED, HOWEVER that B&L shall have the option upon such declaration to request good faith negotiations toward an appropriate amendment to this Agreement in which case both Parties agree to use good faith efforts to negotiate a reasonable amendment to this Agreement; PROVIDED, FURTHER, HOWEVER, that if, after six (6) months from the date of such request for negotiations, the Parties have been unable to reach agreement on the terms of an amendment to this Agreement, either Party may terminate this Agreement.
- 8.2 EFFECT OF TERMINATION. Upon early termination, all data generated, all FDA and other regulatory approvals, and all developmental improvements that are specific to the Catarex Unit but are not specific to the Millennium-TM-system will revert to Optex. To the extent necessary to allow Optex and Optex licensees to commercialize Catarex Products, B&L shall

grant to Optex a worldwide sub-licensable license to B&L Patents, B&L Inventions and Know-how. Such license shall contain a royalty provision which reasonably compensates B&L for its expenses in developing the technologies granted back to Optex, as well as taking into consideration the royalties paid or to have been paid by B&L to Optex for the technology licensed by Optex to B&L.Sections 9.1 (Confidentiality), 12.2 (General Indemnification) and 12.3 (Patent Indemnification) of this Agreement shall survive any termination hereof.

#### 9. EXCHANGE OF INFORMATION AND CONFIDENTIALITY

9.1 CONFIDENTIALITY. Each Party shall keep confidential and shall not publish or otherwise disclose or use for any purpose, other than as provided for in this Agreement, any Know-how or business information provided or made available by the other Party or its Affiliates hereunder (collectively "CONFIDENTIAL INFORMATION"), and neither Party shall, without the prior written consent of the other Party or its Affiliates, as the case may be, use (except as expressly permitted by this Agreement or for the purposes of this Agreement), or disclose to any third Party, any Confidential Information; PROVIDED, HOWEVER, that the foregoing shall not apply to information which the party receiving such information can establish by written documentation to (i) have been publicly known at the time of disclosure by the other party or its Affiliates, as the case may be, (ii) have become publicly known, without fault on its part, subsequent to such disclosure, (iii) have been otherwise known by it from a source (other than the other party or its agents or Affiliates), lawfully having possession of such information, or (v) have been developed by it or its Affiliates independently of the disclosure by the other party or its Affiliates.

The foregoing shall not preclude the disclosure of Confidential Information by either Party:

- (a) to its legal representatives, Affiliates, consultants, outside contractors and (if it has the right to grant the license or sublicense) its licensees and sublicensees, under like confidentiality obligations on the part of the recipients, or
- (b) to the extent required by law or regulation, provided that, to the extent reasonably possible, it shall give prompt written notice of the proposed disclosure to the other party or its Affiliates, as the case may be, so as to allow the other party or its Affiliates, as the case may be, an opportunity to object to such requirement and, if applicable, assure that confidential treatment will be accorded to such information, or
- (c) to the extent that such information is reasonably required to be disclosed for the purpose of securing necessary governmental authorization for the clinical testing or marketing of products or for the purpose of conducting clinical testing or marketing of products, or of prosecuting or defending litigation.
- (d) to the extent that Optex licenses Know-how to third parties outside the Field and disclosure of such Confidential Information is reasonably required in connection therewith; PROVIDED, that such third parties are bound by written confidentiality provisions at least as restrictive as this one.

Additionally, the foregoing shall not preclude the disclosure of Confidential Information by Optex to third parties for use outside the Field provided such third parties are bound by written confidentiality obligations at lease as restrictive as those contained herein.

#### 10. PUBLICITY

- 10.1 INITIAL PRESS RELEASE. The Parties shall issue a mutually acceptable press release upon execution of this agreement.
- 10.2 FUTURE PUBLICITY. Each Party shall have an opportunity to review and comment on any future press releases of the other Party relating to the subject matter of this Agreement.

#### 11. TRADEMARKS AND TRADE NAMES

11.1 Optex shall assign to B&L the Catarex name and any associated trademark rights in connection with the Catarex Products. B&L agrees to fully protect such property, including by way of prosecution and maintenance of any trademark rights. Such property shall be assigned back to Optex upon termination of this Agreement.

#### 12. WARRANTIES, REPRESENTATIONS, AND INDEMNIFICATION

- 12.1 Optex represents and warrants that:
- 12.1.1 it is the owner of the Optex Patents and Know-How and has the right to license the Optex Patents and Know-How free of any lien or encumbrance;
- 12.1.2 it has not assigned or conveyed any interest in the Patent Rights or Know-How which may be inconsistent with the rights granted hereunder;
- 12.1.3 it has no actual knowledge that the manufacture, use, sale, offering for sale or importation of Optex Critical Technology as practiced in Catarex Products will infringe any valid and enforceable United States or foreign patent.
- $12.1.4\ \text{it}$  is not aware that any third party is infringing the Optex Patents; and
- 12.1.5 it has prosecuted all patent applications within the Optex Patents in good faith and has no reason to believe that any Optex Patents would be invalid or would be held to be unenforceable by a court of competent jurisdiction.

#### 12.2 GENERAL INDEMNIFICATION

12.2.1 OPTEX INDEMNITY. Optex shall indemnify and hold harmless B&L and each of its Affiliates, officers, directors, employees and agents from and against any liability, loss, damage, cost and expense, including reasonable attorneys' fees, and expenses ("INDEMNIFIED LOSSES") resulting from or arising out of (i) any material breach of any warranty or material non-performance of any obligation or covenant hereunder, and (ii) any actual or alleged defect in any

products developed by Optex under Section 4.4 (excluding any defect arising out of B&L's failure to perform its responsibilities under Section 4.5).

- 12.2.2 B&L INDEMNITY. B&L shall indemnify and hold harmless Optex and each of its Affiliates, officers, directors, employees and agents from and against any Indemnified Losses resulting from or arising out of (i) a material breach of any warranty or material non-performance by B&L of any covenant or obligation hereunder; (ii) any actual or alleged defect in any products developed by B&L under Section 4.5 hereof (excluding any defect arising out of Optex's failure to perform its responsibilities under Section 4.4) and (iii) B&L's acts relating to the promotion, marketing, labelling and distribution of Catarex Products.
- 12.2.3 INDEMNIFICATION PROCEDURES. Upon the occurrence of an event which requires indemnification under this Agreement (an "INDEMNIFICATION EVENT"), the indemnified party shall give prompt written notice to the indemnifying party providing reasonable details of the nature of the event and the basis of the indemnity claim. The indemnifying party shall then have the right, at its expense and with counsel of its choice, to defend, contest or otherwise protect against any such action. The indemnified party shall also have the right, but not the obligation, to participate at its own expense in the defense thereof with counsel of its choice. The indemnified party shall cooperate to the extent reasonably necessary to assist the indemnifying party in defending, contesting or otherwise protesting against any such action provided that the reasonable out-of-pocket cost in doing so shall be paid by the indemnifying party. the indemnified party fails to promptly notify the indemnifying party of the occurrence of an Indemnification Event and such failure has a material adverse effect on the indemnifying party, the indemnified party shall not be entitled to indemnification with respect to such Indemnification Event. If the indemnifying party fails within thirty (30) days after receipt of such notice (a) to notify the indemnified party of its intent to defend, or (b) to defend, contest or otherwise protect against such suit, action, investigation, claim or proceeding, or fails to diligently continue to provide such defense after undertaking to do so, the indemnified party shall have the right, upon ten (10) days' prior written notice to the indemnifying party, to defend, settle and satisfy any such suit, action, claim, investigation or proceeding and recover the reasonable costs of the same from the indemnifying party.

#### 12.3 PATENT INDEMNITY

- 12.3.1 If B&L must pay a royalty on Net Sales to one or more third parties as a result of infringement of such third party's intellectual property rights by Optex Critical Technology, then fifty percent (50%) of such royalty or royalties shall be deducted by B&L from royalties payable pursuant to Section 3.1.3 of this Agreement for a period of five (5) years from the first such payment by B&L to such third party, provided, however, that in no event shall the royalty payable to Optex under this agreement be reduced to an amount less than a five percent (5%) royalty on Net Sales.
- 12.3.2 If a permanent injunction against the sale of Catarex Products in the United States is issued in the United States for the infringement of third party intellectual property rights by Optex Critical Technology, then Optex shall return to B&L any amounts paid to Optex as Milestone II and Milestone III payments; PROVIDED, HOWEVER, that any such repayment

obligations of Optex shall be reduced by an amount equal to twenty-five percent (25%) of Net Sales made prior to the issuance of such permanent injunction. In the event of an award of damages for such infringement by Optex Critical Technology, then fifty percent (50%) of such award of damages shall be payable to B&L by Optex for a period of five (5) years from the First Commercial Use, except that any such amount payable by Optex shall not exceed the sum of (i) royalties actually received by Optex from B&L pursuant to Section 3.1.3, and (ii) fifty percent (50%) of the difference between Milestones received by Optex and Milestones returned by Optex to B&L under this Agreement.

#### 13. GOVERNING LAW, DISPUTE RESOLUTION

- 13.1 GOVERNING LAW. This Agreement shall be governed by and construed in accordance with, the laws of the State of California without giving effect to principles of conflict of laws.
- 13.2 DISPUTE RESOLUTION. Any dispute between the Parties will be referred to the Chief Executive Officers of B&L and Optex (or their designees) for good faith resolution, for a period of ninety (90) days. If such dispute is not resolved by the end of such ninety (90) day period, the Parties shall be free to pursue any legal or equitable remedy available to them.

#### 14. MISCELLANEOUS

- 14.1 ASSIGNMENT. This Agreement and all rights and obligations hereunder are personal to the parties, and may not be assigned except to an affiliate of a Party without the express prior written consent of the other Party. Any assignment or attempt at same in the absence of such prior written consent shall be void and without effect.
- 14.2 FORCE MAJEURE. Neither Party shall be responsible or liable to the other hereunder for failure or delay in performance of this Agreement due to any war, fire, accident or other casualty, or any labor disturbance or act of God or the public enemy, or any other contingency beyond such Party's reasonable control. In addition, in the event of the applicability of this Section, the Party affected by such force majeure shall use reasonable efforts, consistent with good business judgment, to eliminate, cure and overcome any of such causes and resume performance of its obligations.
- 14.3 SEPARABILITY. If any portion of this Agreement is determined to be illegal or otherwise unenforceable by agreement of the Parties, by an arbitrator, by a court of competent jurisdiction or by an administrative agency of competent jurisdiction, such section, to the extent permitted by law, shall be treated as deleted from this Agreement and the remaining portions of this Agreement shall continue to be in full force and effect according to the terms hereof.
- 14.4 ENTIRE AGREEMENT. This Agreement contains the entire and only agreement between the Parties with respect to the manufacture and sale of the Product and no oral statements or representations or written matter not contained in this Agreement shall have any force or effect. This Agreement shall not be amended or modified in any way except by a writing executed by authorized representatives of both Parties.

- 14.5 MODIFICATIONS. Any modification or addition to this Agreement shall be valid only if it is confirmed in writing by the duly authorized officers of both Parties.
- 14.6 NOTICES. Any notice, request, instruction or other communication required or permitted to be given under this Agreement shall be in writing and shall be given by sending such notice properly addressed to the other Party's address shown below (or any other address as either Party may indicate by notice in writing to the other from time to time) (i) by hand or by prepaid registered or certified mail, return receipt requested, in either of such cases which notice shall be deemed delivered upon receipt, (ii) via telecopy or telegram, in either of such cases which notice shall be deemed delivered upon receipt, or (iii) via nationally recognized overnight courier, in which case such notice shall be deemed delivered upon receipt. All such notices shall be deemed given when received.

If to Optex: Atlantic Pharmaceuticals, Inc.

1017 Main Campus

Suite 3900

Raleigh, North Carolina 27606 Attention: Chief Executive Officer

with a copy to: Brobeck, Phleger & Harrison LLP

2200 Geng Road

Two Embarcadero Place

Palo Alto, California 94303

Attention: J. Stephan Dolezalek, Esq.

If to B&L: Bausch & Lomb Surgical

555 West Arrow Street Claremont, California 91711

Attention: President

with a copy to: Bausch & Lomb Surgical

555 West Arrow Street
Claremont California 917

Claremont, California 91711 Attention: General Counsel

- 14.7 HEADINGS. The headings and captions used in this Agreement are for the convenience of reference only and shall not be construed as part of this Agreement or as a limitation on the scope of any provisions of this Agreement.
- 14.8 WAIVER. The failure of either Party to terminate or seek redress for a breach of, or to insist upon strict performance of any term, covenant, condition or provision contained in this Agreement shall not prevent a similar subsequent act from constituting a breach of this Agreement.
- 14.9 NO AGENCY. Nothing herein shall be deemed to constitute either Party as the  $\,$

agent or representative of the other Party, or both Parties as joint venturers or partners for any purpose. Except as set forth herein, neither Party shall be responsible for the acts or omissions of the other Party, and neither Party will have authority to act on behalf of, represent or obligate the other Party in any way without prior written authority from the other Party.

**OPTEX** 

By: /s/ J.D. Lindjord

J.D. Lindjord

President and Chief Executive Officer

BAUSCH & LOMB SURGICAL

By: /s/ Robert H. Blankenmeyer
Robert H. Blankenmeyer
Chief Operating Officer

18.