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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) December 16, 2002

BioDelivery Sciences International, Inc.
(Exact name of registrant as specified in its charter)

Delaware	0-28931	35-2089858
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

UMDNJ Medical School 185 South Orange Avenue, Bldg #4 Newark, New Jersey	07103
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code (813) 902-8980

Not Applicable
(Former name or former address, if changed since last report)

Item 5. Other Events and Regulation FD Disclosure.

(a) On December 31, 2002, BioDelivery Sciences International, Inc., a Delaware corporation (the "Company") entered into an agreement with Pharmaceutical Product Development, Inc, a North Carolina corporation ("PPDI"), pursuant to PPDI was granted a license to apply the Company's bioral nano-delivery technology to two therapeutic products. The terms of the license require one upfront royalty payment to the Company, additional royalty payments based on regulatory milestones and a running royalty rate based on worldwide sales.

(b) As previously announced, the Company is a party to a license agreement with The University of Medicine and Dentistry of New Jersey and Albany Medical College (collectively, the "Universities") regarding certain of its technologies. On December 16, 2002, the Company and the Universities amended such agreement to provide for a decrease in the royalty payments to be paid to the Universities on sublicenses in consideration of an increase in the royalty on BDSI product sales and the issuance to the Universities of options to purchase shares of Company common stock.

(c) On January 6, 2003, the Company announced that it entered into a confidential evaluation agreement with a major pharmaceutical company for encochleation of a proprietary antimicrobial. The Company will be paid for its services related to the evaluation. In exchange, the pharmaceutical company was granted an exclusive option to negotiate a license for application of the Bioral(TM) delivery technology to its antimicrobial pharmaceutical.

Item 7. Financial Statements and Exhibits.

Set forth below is a list of Exhibits included as part of this Current Report.

10.1 Sub-License Agreement, effective as of December 31, 2002, by and between the Company and Pharmaceutical Product Development, Inc. (confidential treatment requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2).

99.1 Press Release of the Company, dated January 6, 2003, relating to the license agreement between the Company and PPDI and confidential evaluation agreement.

SIGNATURES

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

January 7, 2003 BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ Francis E. O'Donnell, Jr.

Name: Francis E. O'Donnell, Jr.
Title: President and Chief Executive Officer

EXHIBIT 10.1

CONFIDENTIAL TREATMENT REQUESTED
WITH RESPECT TO CERTAIN PORTIONS HEREOF
DENOTED WITH "***"

SUB-LICENSE AGREEMENT
BETWEEN
BIODELIVERY SCIENCES INTERNATIONAL, INC.
AND
PHARMACEUTICAL PRODUCTS DEVELOPMENT, INC.
DATED AS OF
December 31, 2002

This Sub-License Agreement (this "Agreement") effective as of December 31, 2002, by and between BIODELIVERY SCIENCES INTERNATIONAL, INC., a Delaware corporation, having its principal place of business at 185 South Orange Avenue, Administrative Building No. 4, Newark, NJ 07103 ("BDSI") and PHARMACEUTICAL PRODUCT DEVELOPMENT, INC., a North Carolina corporation, having its principal place of business at 3151 South Seventeenth Street, Wilmington, NC 28412 ("PPDI") (collectively the "Parties").

WITNESSETH:

Whereas, BDSI has rights to certain Licensed Technology (hereinafter defined) relating to cochleates, cochleate derivatives, and proteoliposomes, and nano-encapsulation;

Whereas, PPDI recognizes that the Licensed Technology represents a valuable means of delivering Component Products for the use and/or sale in the treatment or prevention of human and/or animal diseases;

Whereas, PPDI wishes to enter into an agreement to obtain exclusive licenses for specific Component Products which utilize Licensed Technology in the Field (hereinafter defined) from BDSI in order to research, develop and commercialize therapeutic products made in accordance therewith; and

WHEREAS, BDSI is willing to grant such licenses to PPDI under the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the various promises and undertakings set forth herein, the Parties agree as follows:

ARTICLE 1 - DEFINITIONS

As used herein, capitalized terms shall have the following meanings:

1.1 "Affiliate", with respect to any Party, shall mean any person or entity controlling, controlled by, or under common control with such Party. For these purposes, "control" shall refer to (i) the possession, directly or indirectly, of the power to direct the management or policies of a person or entity, whether through the ownership of voting securities, by contract or otherwise or (ii) the ownership, directly or indirectly, of at least 50% of the voting securities or other ownership interest of a person or entity.

1.2 "BDSI Personnel" means any BDSI employee, intern or consultant who participates in any Sponsored Research Program or any PPDI Evaluation Program in any manner or who acquires knowledge of any test data, clinical information or any other information resulting from any Sponsored Research Program or any PPDI Evaluation Program which is deemed a trade secret or confidential or proprietary to PPDI or BDSI, such as an independent contractor (including any consultant under an obligation of confidentiality), or any research collaborator.

1.3 "Commercial Sale" shall mean any sale which transfers physical possession and title to any Licensed Product (hereinafter defined) to a Third Party in exchange for value and after which transfer the seller has no right or power to determine the Third Party's resale price. Transfer for research, development or

testing purposes shall not constitute a Commercial Sale.

1.4 "Component Product" shall mean any *** Product, *** Product or *** Product. CONFIDENTIAL TREATMENT REQUESTED

1.5 "*** Products" shall mean ***. CONFIDENTIAL TREATMENT REQUESTED

1.6 "Effective Date of this Agreement" shall mean the date first written above.

1.7 "Evaluation Agreement" shall mean the letter agreement between BDSI and PPDI, dated November 4, 2002, attached hereto as Exhibit A.

1.8 "Field" shall mean delivery of Component Products to all living systems for health care applications.

1.9 "First Commercial Sale" means the first Commercial Sale.

1.10 "Joint Invention" shall mean any Invention for which it is determined, in accordance with applicable law, that both: (i) employees or agents of PPDI or any other persons obligated to assign such Invention to PPDI, and (ii) BDSI Personnel or any other persons obliged to assign such Invention to BDSI, are joint inventors of such Invention.

1.11 "Licensed Patents" shall mean any current and future Patent, owned or controlled by BDSI, or any of the same jointly owned or controlled by BDSI and that relate to the Licensed Technology, including Patents set forth on Exhibit B.

1.12 "Licensed Product" shall mean any Component Product that is in suitable form for Commercial Sale.

1.13 "Licensed Technology" shall mean any and all information, and all patentable and non-patentable inventions (including, without limitation, all Inventions and Joint Inventions), improvements, discoveries, claims, formulae, processes, methods, trade secrets, technologies, data and know-how owned, licensed or controlled by BDSI or to which BDSI has the right to grant licenses or sublicenses before or during the term of this Agreement: (i) related to the cochleate, cochleate derivatives, proteoliposome, and nano-encochleation technology described in Exhibit C, (ii) claimed, covered or disclosed in any patent or patent application listed in Exhibit B which relates to the cochleate, cochleate derivative, proteoliposome nano-encochleation technology described in Exhibit C, or (iii) derived from any Sponsored Research Program (hereinafter defined) or any PPDI Evaluation Program (hereinafter defined).

1.14 "Net Sales" shall mean the gross amount invoiced for all Licensed Products sold by PPDI and/or its Affiliates in arm's length sales or commercial transactions to a Third Party (excluding sales to Sublicensees for their resale), less deductions for:

(a) commissions, trade, quantity and cash discounts or rebates actually allowed or given;

(b) credits, allowances or refunds given or made for rejected, outdated or returned Components, if applicable;

(c) any tax or government charge (other than an income tax) levied on the sale, transportation or delivery of a Licensed Product and borne by the seller thereof;

(d) any prepaid or invoiced charges for freight, postage, shipping, import or export taxes, insurance or charges for returnable containers; and

(e) in those cases when the cost to PPDI of manufacturing or supplying a Component is at least as great as the fair market value thereof, PPDI's fully-allocated cost for the manufacture or supply of the Component.

1.15 "*** Product" shall ***. CONFIDENTIAL TREATMENT REQUESTED

1.16 "Party" shall mean PPDI or BDSI and, when used in the plural, shall mean PPDI and BDSI.

1.17 "Patent" means (i) unexpired letters patent (including inventor's certificates) which have not been held invalid or unenforceable by a court of competent jurisdiction from which no appeal can be taken or has been taken within the required time period, including without limitation any substitution, extension, registration, confirmation, reissue, re-examination, renewal or any like filing thereof and (ii) pending applications for letters patent, including without limitation any continuation, division or continuation-in-part thereof and any provisional applications.

1.18 "*** Product" shall mean ***. CONFIDENTIAL TREATMENT REQUESTED

1.19 "PPDI Evaluation Program" shall mean any research and development conducted by or on behalf of PPDI pursuant to the Evaluation Agreement.

1.20 "Publication" means any written or oral publication or disclosure resulting from or involving the Licensed Technology or the subject matter of any Sponsored Research Program or PPDI Evaluation Program, and includes but is not limited to a publication or disclosure in books, journals, theses, the media, trade publications, scientific meetings, poster sessions, and symposia.

1.21 "Sponsored Research Program" shall mean any research conducted by BDSI, in collaboration with PPDI.

1.22 "Sublicensee" shall mean any Third Party granted a sublicense by PPDI pursuant to Section 3.3 hereof.

1.23 "Territory" shall mean the entire world.

1.24 "Third Party" means any person or entity other than PPDI, BDSI or any Affiliate of either PPDI or BDSI.

1.25 "Valid Claim" shall mean a claim of any issued or granted Licensed Patent which has not been held invalid or unenforceable by final decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which is not admitted to be invalid or unenforceable through reissue, disclaimer or otherwise.

ARTICLE 2 - REPRESENTATIONS AND WARRANTIES

2.1 Representations and Warranties of Both Parties. Each Party represents and warrants to the other Party that: (i) it is free to enter into this Agreement; (ii) in so doing, it will not violate any other agreement to which it is a party; and (iii) it has taken all corporate action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement.

2.2 Representations and Warranties of BDSI. BDSI hereby represents and warrants that:

(a) BDSI either owns or licenses all of the Licensed Patents listed on Exhibit B, and has the exclusive right to grant licenses and sublicenses therefore without the consent or approval of any Third Party, except as provided in Section 2.3;

(b) BDSI own or licenses all of the Licensed Technology in existence on the date of this Agreement, and has the right to grant licenses and sublicenses therefore without the consent or approval of any Third Party;

(c) To the best of BDSI's knowledge, all the Licensed Patents listed on Exhibit B are in full force and effect and have been maintained to date;

(d) BDSI is not aware of any asserted or unasserted claim or demand against the Licensed Technology;

(e) To the best of BDSI's knowledge, none of the Licensed Technology infringes upon any patent or other proprietary rights of any other Third Party; and

(f) BDSI has not entered into any agreement with any Third Party which is in conflict with the rights granted to PPDI pursuant to this Agreement.

2.3 Disclaimer of Other Warranties. EXCEPT AS PROVIDED HEREIN, THE LICENSED TECHNOLOGY IS PROVIDED WITHOUT WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER WARRANTY, EXPRESS OR IMPLIED. EXCEPT AS EXPRESSLY PROVIDED, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY THAT THE

LICENSED TECHNOLOGY WILL NOT INFRINGE ANY PATENT OR OTHER PROPRIETARY RIGHT OF A THIRD PARTY.

2.4 Employee Agreements. Each Party warrants that it has, and covenants that it will have, entered into a proprietary information and inventions agreement with each of its employees prior to the time that any such employee shall receive confidential information from a disclosing party or begin work related to this Agreement. Such agreement shall minimally set forth employee obligations to assign inventions to the inventing Party and to maintain confidentiality of confidential information consistent with the terms of this Agreement.

ARTICLE 3 - LICENSE GRANT

3.1 Grant of License. Subject to the terms and conditions of this Agreement, BDSI hereby grants to PPDI an exclusive license throughout the Territory, with the right to grant sublicenses (subject to Sections 3.4 and 3.5), to make, use or sell Licensed Technology and Licensed Patents in the Field for research, development and commercialization of one *** Product and one *** Product or *** Product. CONFIDENTIAL TREATMENT REQUESTED

3.2 Reservation of Rights. The license granted in Section 3.1 of this Agreement is subject to a reserved right in BDSI to make, use and sell Licensed Technology and Licensed Patents for any *** Product, *** Product or *** Product for which BDSI has not given consent to PPDI for development of a Licensed Product pursuant to Section 3.3 or that is not the subject of an Evaluation Agreement or a Sponsored Research Agreement. After BDSI has consented to the development of any *** Product, *** Product or *** Product, or a *** Product, *** Product or *** Product becomes the subject of an Evaluation Agreement or a Sponsored Research Agreement, BDSI shall not thereafter, directly or indirectly, make, use or sell the Licensed Technology or Licensed Patents for research, development or commercialization of any such *** Product, *** Product or *** Product. CONFIDENTIAL TREATMENT REQUESTED

3.3 *** Product Approval. Prior to developing a *** Product, *** Product or *** Product, PPDI will notify BDSI in writing regarding the identity of such Product and PPDI's intent to develop the same ("Product Development Notification"). BDSI shall notify PPDI in writing of its consent to PPDI's request to develop a *** Product, *** Product or *** Product within thirty (30) days of receipt of a Product Development Notification. In the event that BDSI fails to provide a written response to PPDI within the 30-day period, then BDSI shall be deemed to have consented to PPDI's request to develop a *** Product, *** Product or *** Product. BDSI agrees that consent shall not be withheld unless BDSI clearly demonstrates that PPDI's proposed *** Product, *** Product or *** Product will conflict with a product being developed by BDSI. In the event that BDSI refuses consent, BDSI shall provide to PPDI a written statement describing BDSI's product and the basis for withholding consent. BDSI shall provide PPDI with written notification of any *** Product, *** Product or *** Product under development by BDSI using Licensed Technology. PPDI shall not be obligated to obtain consent for any *** Product, *** Product or *** Product that is the subject of an Evaluation Agreement or a Sponsored Research Agreement. CONFIDENTIAL TREATMENT REQUESTED

3.4 Right to Grant Sublicenses. PPDI shall have the right to sublicense the License Technology. Each sublicense granted by PPDI pursuant to this Agreement, shall be consistent the provisions of this Agreement. Prior to the grant of each sublicense hereunder, PPDI shall provide BDSI a redacted copy of the sublicense.

3.5 PPDI Responsibility for Sublicense. PPDI shall be responsible for and guarantees the performance of its Sublicensees, including the payment of all royalties to BDSI as provided in Article 4 as though PPDI itself had sold the Licensed Product and the provision of sales and other reports hereunder. Upon termination of this Agreement, all sublicenses shall revert directly to BDSI, which may at its election recognize or disaffirm each such sublicense on a case-by-case basis.

3.6 Inventions.

(a) Pre-Existing Rights. Except as expressly provided herein or in an Exhibit, nothing in this Agreement shall be construed as a grant to either party of any ownership or other interest in any copyrights, patents, trademarks, know-how, inventions, trade secrets and registrations and applications for the registration thereof ("Intellectual Property") of the other created on or before the Effective Date.

(b) *** Products. Except as expressly provided in subsection (c) below, any and all Intellectual Property developed by the Parties, either solely or jointly, during the development of a Licensed Product by PPDI shall be the sole and exclusive property of PPDI. BDSI agrees to reasonably cooperate with PPDI to execute, or cause BDSI Personnel to execute, any documents necessary or desirable to secure or perfect PPDI's legal rights and worldwide ownership in such Intellectual Property, including, but not limited to documents relating to patent, trademark and copyright applications, at PPDI's expense. BDSI shall not at any time, in any manner, during or after this Agreement, under any circumstances, be entitled to or claim any right, title or interest herein or any commission, fee or other direct or indirect benefit from PPDI or Affiliate, in respect of such Intellectual Property created by BDSI hereunder. CONFIDENTIAL TREATMENT REQUESTED

(c) Exclusion. Intellectual Property shall not include any improvements to Licensed Patents that exist independently of the *** Product or Licensed Product ("BDSI Intellectual Property"). Whether BDSI Intellectual Property results from PPDI's efforts or the joint efforts of the Parties, all BDSI Intellectual Property shall be the exclusive property of BDSI, subject, however, to the royalty-free license granted to PPDI in Section 3.7 below. CONFIDENTIAL TREATMENT REQUESTED

3.7 License to BDSI Intellectual Property. BDSI hereby grants to PPDI a fully-paid, worldwide, non-exclusive license to BDSI Intellectual Property. BDSI shall immediately notify PPDI in writing of the development of any BDSI Intellectual Property and this Agreement shall be amended effective as of the date of such notice to add such BDSI Intellectual Property to Licensed Technology and/or Licensed Patents without any further action on the part of either party.

3.8 ***. CONFIDENTIAL TREATMENT REQUESTED.

ARTICLE 4 - ROYALTY PAYMENTS AND REPORTS

4.1 License Fee. In consideration of the license grant set forth in this Agreement, PPDI shall pay to BDSI *** within thirty (30) days of the Effective Date.

4.2 ***. CONFIDENTIAL TREATMENT REQUESTED

4.3 Milestone Payments. In addition to the other payments required to be made by PPDI, its Sublicensee and Affiliates hereunder, PPDI shall pay to BDSI the following one-time milestone payments (each a "Milestone Payment" and

collectively the "Milestone Payments") with respect to each Licensed Product as follows:

*** [text omitted relating to Milestone Payments]. CONFIDENTIAL TREATMENT REQUESTED.

4.4 Running Royalty. In consideration of the license rights set forth in Article 3 hereof, PPDI shall, during the periods specified in Section 4.6, pay earned royalties on the Commercial Sale of Licensed Products based on Net Sales of all Licensed Products by PPDI and its Affiliates and Sublicensee(s) at the rate of *** ("Running Royalty"). CONFIDENTIAL TREATMENT REQUESTED

BDSI agrees to discuss with PPDI and give due consideration to PPDI's views as to other appropriate and reasonable reductions of such rate at any time that PPDI believes that market conditions make it economically unreasonable to pay BDSI a Running Royalty at the rates above on any Licensed Product. Running Royalty payments may be offset by credits only as provided in Sections 4.5 hereof.

4.5 Credits. ***. CONFIDENTIAL TREATMENT REQUESTED

4.6 Term of Running Royalty Obligations. The Milestone Payment and Running Royalty obligations specified in Sections 4.3 and 4.4 above shall continue as to each Licensed Product in the Territory for the term of the last to expire of the Licensed Patent rights covering the Licensed Product.

4.7 Date and Place of Sale. Licensed Products shall be considered sold when PPDI, an Affiliate or Sublicensee is paid by a purchaser for a Licensed Product.

4.8 Payments by PPDI. Running Royalties and Milestone Payments accruing to BDSI pursuant to Sections 4.3, 4.4 and 4.7 shall be paid by PPDI to BDSI no later than sixty (60) days following the end of the calendar half-year during which such Running Royalties or Milestone Payments accrued.

4.9 Place of Payment. All Running Royalty payments due BDSI shall be payable in United States dollars by wire transfer to a bank account designated by BDSI from time to time. PPDI shall convert all non-U.S. dollar sales to U.S. dollars using the average exchange rates quoted in the Wall Street Journal for the final day of each month in the relevant period for which the Running Royalty is being paid. In the event payment of any Running Royalties is restricted or prohibited by the laws or regulations of a particular country, then to the extent of such a restriction and prohibition, Running Royalties shall be paid to BDSI in that country and in the currency of said country into an account to be designated by BDSI.

4.10 Third Party Consideration. In the case of a Commercial Sale other than in an arm's-length transaction exclusively for money, such as barter or counter-trade, the amount of such Sale shall be calculated using the fair market value of such Licensed Product (if higher than the stated sales price) in the country of disposition.

4.11 Taxation of Payments.

(a) Insofar as any payment that is due BDSI under this Agreement is subject to any tax, duty, levy, or other government imposition, BDSI agrees to bear any and all such taxes, duties, levies or impositions. BDSI hereby

authorizes PPDI to withhold such taxes, duties, levies or impositions from the payments which are payable to BDSI in accordance with this Agreement if PPDI is required to do so under the laws of the United States or any country in the Territory where such taxes, duties, levies or impositions are payable. Whenever PPDI deducts such tax, duty, levy or imposition from any payments due BDSI, then PPDI shall furnish BDSI with a certificate

showing the payment of thereof to the United States or any country in the Territory.

(b) In the event the Running Royalty payments which are due to BDSI under this Agreement are subject to value added taxation by any government, then BDSI shall bear such value added tax in full and PPDI shall be reimbursed therefor. If appropriate, BDSI may add such value added taxes to its royalty accounts, provided such value added taxes are credited against PPDI's value added tax debt and PPDI is reimbursed in full with respect thereto. Notwithstanding anything herein to the contrary, PPDI shall have no liability for any value added tax directly or indirectly relating to the Running Royalties.

(c) In the event any payment by PPDI to BDSI is subject to a withholding or other income tax in any country in the Territory, PPDI shall so advise BDSI promptly following PPDI becoming aware of the applicability of any such tax. BDSI shall have the right to contest with the appropriate governmental body any such proposed withholding and PPDI shall provide, at BDSI's expense, reasonable cooperation to BDSI in any such contest. PPDI shall provide BDSI with such receipts or other evidence of any tax withheld as is necessary for BDSI to claim any credit or deduction available to it in other jurisdictions. Payments to BDSI shall only be reduced for withholding taxes imposed by the jurisdiction out of which the payment is directly made to the BDSI.

4.12 Interest. All payments due hereunder from PPDI that are not paid to BDSI when due and payable as specified in this agreement shall bear interest at an annual rate equal to the prime rate ("Prime Rate") for U.S. dollar deposits in effect from time to time, as published daily in the Wall Street Journal plus 2%, compounded monthly from the date due until paid, or at such lower rate of interest as shall then be the maximum rate permitted by applicable law.

4.13 Right to Documentation. Upon request, BDSI shall have the right to request reasonable documentation of PPDI's calculations to determine PPDI's Net Sales for the Licensed Products and to request discussion of such calculations with appropriate representatives of PPDI.

4.14 Records Retention. PPDI, its Sublicensee and Affiliates shall keep complete and accurate records pertaining to the sale of Licensed Products in the Territory and covering all transactions which Net Sales are derived for a period of three (3) calendar years after the year in which such sales occurred, and in sufficient detail to permit BDSI to confirm the accuracy of Running Royalty calculations hereunder.

4.15 Audit Request. At the request and expense of BDSI, PPDI, its Affiliates and Sublicensees shall permit an independent, certified public accountant appointed by BDSI acceptable to PPDI or its Affiliates, at reasonable times and upon reasonable notice, to examine those records and all other material documents relating to or relevant to Net Sales and Sublicensee income in the possession or control of PPDI, its Affiliates or Sublicensees, for a period of three (3) years after such Running Royalties have accrued, as may be necessary to: (i) determine the correctness of any report or payment made under this Agreement; or (ii) obtain information as to the Running Royalties payable for any calendar quarter in the case of PPDI's or its Affiliate's failure to report or pay pursuant to this Agreement. Said accountant shall not disclose to BDSI any information other than information relating to said reports, Running Royalties, and payments. Results of any such examination shall be made available to both Parties. BDSI

shall bear the full cost of the performance of any such audit, unless such audit demonstrates underpayment of royalties by PPDI of more than ten percent (10%) from the amount of the original Running Royalty payment made by PPDI. In such event, PPDI shall bear the full cost of the performance of such audit. BDSI shall have no right to audit or seek payment of any Running Royalties for any Commercial Sale after the date which is three years from the date of such Commercial Sale.

ARTICLE 6 - PATENT PROSECUTION; ENFORCEMENT; INFRINGEMENT

6.1 Patent Prosecution and Maintenance.

(a) BDSI shall continue to have full responsibility for and shall control the preparation and prosecution of all Patents and the maintenance of all Patents related to the Licensed Technology and included in the Licensed Patents, provided that all actions related thereto requested by PPDI, including, without limitation, the filing and prosecution of foreign Patents, shall be taken by BDSI and PPDI shall be a full participant in the preparation and review of all filings. BDSI agree to take all actions reasonably necessary to diligently prosecute and maintain any Patents in the countries which PPDI determines Patents will be filed and prosecuted, and where the Patents will be maintained. The Parties acknowledge and agree that they intend for BDSI to file and prosecute Patents and maintain patents in all major commercial markets where viable Patent protection is available.

(b) BDSI shall use qualified independent patent counsel to file and prosecute all patent applications required pursuant to Section 6.1(a). PPDI or its representatives shall be entitled to meet and confer with such patent counsel at reasonable times and places. BDSI shall promptly provide copies to PPDI of any communications from any patent office relating to the Licensed Technology or the Licensed Patents, and allow PPDI and its patent counsel the opportunity to attend (either in person or by phone) any conferences (conducted in person or by phone) to be made with or to any patent office regarding the Licensed Technology or the Licensed Patents. In addition, filing deadlines permitting, at least thirty (30) days prior to the filing of any patent application, amendment thereto, or response to any patent office action related to the Licensed Technology or the Licensed Patents, BDSI shall provide PPDI with a copy of each such patent application, amendment or response and will provide PPDI and its legal counsel with an opportunity to consult with BDSI and its patent counsel regarding the filing and contents of any such application, amendment or response, and the advice and suggestions of PPDI and its legal counsel shall be seriously taken into consideration by BDSI and its legal counsel in connection with such filing. BDSI shall also provide PPDI with copies of any patentability search reports made by patent counsel, including Patents located, a copy of each Patent, and each Patent that issues thereon.

(c) In accordance with Section 3.5(b) hereof, PPDI shall be solely responsible for the preparation, filing, prosecution and maintenance of all Patents relating to Intellectual Property. BDSI agrees to reasonably cooperate with PPDI to document ownership of such Intellectual Property rights according to Section 3.5(b) hereof, including without limitation, obtaining execution of separate assignment documents for recordation purposes in the applicable patent offices. BDSI further agrees to reasonably cooperate in the preparation and prosecution of patent applications on such Intellectual Property pursuant to Section 3.5(b) hereof. In the event that PPDI does not desire to proceed with the prosecution of a Patent and indicates such by written notice, BDSI may obtain such Patent at no cost to PPDI.

(d) Except as provided for above in Section 6.1(c), in the event that the Parties elect to file one or more Patents comprising Joint Inventions, the Parties shall confer on how the preparation and prosecution of such applications shall be accomplished. Once the Parties agree on how to proceed with respect to the preparation and filing of Patents comprising Joint Inventions, all other provisions of this Section 6.1 shall govern such preparation, filing, maintenance and prosecution.

(e) Both Parties agree to cooperate with the other Party to execute all lawful papers and instruments, to make all rightful oaths and declarations and to provide consultation and assistance as may be necessary in the preparation, prosecution, maintenance, and reinforcement of all such Patents.

6.2 Limitations on Publications. The Parties agree that no one Party shall

publish the results of any studies, whether conducted by its own employees or in conjunction with a Third Party, carried out pursuant to this Agreement or confidential information received from the other Party that is relating to a Component or Licensed Product, without the prior written approval of the other Party. Each Party agrees to provide the other Party with a copy of any proposed abstracts, presentations, manuscripts, or any other disclosure which discloses clinical study results pursuant to this Agreement or confidential information received from the other Party at least one hundred twenty (120) days prior to their intended submission for publication and agrees not to submit or present such disclosure until the Party not seeking to disclose such information provides its prior written approval. Such written approval will not be unreasonably withheld unless such proposed disclosure could reasonably harm or impair a Party's intellectual property assets or may reasonably cause commercial harm to a Party.

6.3 Notification of Infringement. If either Party learns of an infringement or threatened infringement by a Third Party of any Licensed Patent granted hereunder within the Territory, such Party shall promptly notify the other Party and shall provide such other Party with available evidence of such infringement. Section 6.3 shall then be applicable.

6.4 Patent Enforcement. BDSI shall have the first right, but not the duty, to institute patent infringement actions against third parties based on any Licensed Patent under this Agreement. If BDSI does not institute an infringement proceeding against an offending Third Party within ninety (90) days after receipt of notice from PPDI, PPDI shall have the right, but not the duty, to institute such an action. The costs and expenses of any such action (including fees of attorneys and other professionals) shall be borne by the Party instituting the action, or, if the Parties elect to cooperate in instituting and maintaining such action, such costs and expenses shall be borne by the Parties in such proportions as they may agree in writing. Each Party shall execute all necessary and proper documents and take such actions as shall be appropriate to allow the other Party to institute and prosecute such infringement actions. Any award paid by third parties as a result of such an infringement action (whether by way of settlement or otherwise) shall be paid to the Party who instituted and maintained such action, or, if both Parties instituted and maintained such action, such award shall be allocated among the Parties in proportion to their respective contributions to the costs and expenses incurred in such action.

6.5 Infringement Action by Third Parties.

(a) In the event of the institution of any claim or suit by a Third Party against PPDI for patent infringement involving the manufacture, use, lease or sale of any Licensed Product in the Territory, PPDI shall promptly notify BDSI in writing of such claim or suit. PPDI shall have the right to defend such claim or suit at its own expense, and BDSI hereby agrees to assist and cooperate with PPDI, at BDSI's own expense, to the extent

necessary in the defense of such claim or suit. During the pendency of such claim or suit, PPDI shall continue to make all payments due under this Agreement, but shall have a credit against Milestone Payments and Running Royalties otherwise payable hereunder for the full amount of all costs and expenses incurred by PPDI in defending against such claim or suit; provided, however, that in applying the credit against any Milestone Payments or Running Royalty payment, the amount of such payment shall not be reduced by more than 50% and any remaining credit shall be applied against subsequent Milestone Payments or Running Royalty payments .

(b) If as a result of any judgment, award, decree or settlement resulting from a claim or action instituted by a Third Party, PPDI is required to pay a royalty or other amounts to such Third Party ("Third Party Royalty"), PPDI shall continue to pay Running Royalties for such Licensed Products in the country which is the subject of such action, but shall be entitled to a credit against such payments in an amount equal to the Third Party Royalty, but in no event shall such credit be more than the Running Royalties due hereunder for such Licensed Products in such country

which is the subject of such action and any remaining credit shall be applied against subsequent Milestone Payments or Running Royalty payments. In addition, if PPDI is required to pay damages to such Third Party, and such damages are not otherwise reimbursed by BDSI, PPDI shall be entitled to a credit against Running Royalty payments in an amount equal to such damages, to the extent paid by PPDI to such Third Party, but in no event shall the total credit provided hereunder be more than such Running Royalties due hereunder for such Licensed Products in such country which is the subject of such action.

ARTICLE 7 - CONFIDENTIALITY

7.1 Use of Name. BDSI agree not to use directly or indirectly PPDI's name without PPDI's prior written consent. PPDI agrees not to use directly or indirectly BDSI's name or information without BDSI's prior written consent. Notwithstanding the foregoing, PPDI and BDSI may include an accurate description of the terms of this Agreement to the extent required under federal or state securities or other disclosure; and PPDI may use BDSI's names in various documents used by PPDI for capital raising and financing purposes.

7.2 Confidentiality; Exceptions. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that, for the term of this Agreement and for three (3) years thereafter, the receiving Party shall keep completely confidential and shall not publish or otherwise disclose and shall not use for any purpose other than proper performance hereunder any information furnished to it by the other Party pursuant to this Agreement, except to the extent that it can be established by the receiving Party by competent proof that such information:

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

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

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

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

(e) was independently developed by or for the receiving Party by persons not having access to such information, as determined by the written records of such party.

Each Party may disclose the other's information to the extent such disclosure is reasonably necessary in filing or prosecuting Patents, prosecuting or defending litigation, complying with applicable governmental regulations, undertaking basic research with outside collaborators, or conducting preclinical or clinical trials provided that if a Party is required by law to make any such disclosure of the other Party's secret or confidential information it will, except where impracticable for necessary disclosures, for example to physicians conducting studies or to health authorities, give reasonable advance notice to the other Party of such disclosure requirement and, except to the extent inappropriate in the case of patent applications, will use its best efforts to secure confidential treatment of such information required to be disclosed.

ARTICLE 8 - INDEMNIFICATION

8.1 Indemnification by PPDI. PPDI shall defend, indemnify and hold BDSI, its officers, directors, employees and consultants harmless from and against any and all Third Party claims, suits or demands, threatened or filed, ("Claims") for liability, damages, losses, costs and expenses (including the costs and expenses of attorneys and other professionals), at both trial and appellate levels, relating to the distribution, testing, manufacture, use, lease, sale,

consumption on or application of Licensed Products by PPDI, its Affiliates or its Sublicensees pursuant to this Agreement, including, without limitation, claims for any loss, damage, or injury to persons or property, or loss of life, relating to the promotion and advertising of Licensed Products and/or interactions and communications with governmental authorities, physicians or other Third Parties relating to the Licensed Products. The foregoing indemnification shall not apply to any Third Party Claims to the extent are caused by the negligence of BDSI.

8.2 Indemnification by BDSI. BDSI shall defend, indemnify and hold PPDI, its officers, directors, employees and consultants harmless from and against any and all Third Party Claims for liability, damages, losses, costs and expenses (including the costs and expenses of attorneys and other professionals), at both trial and appellate levels, relating to BDSI's activities contemplated under this Agreement, including, but not limited to, (a) breach of the representations, warranties and obligations of BDSI hereunder, or (b) any tax, duty, levy or government imposition on any sums payable by PPDI to BDSI hereunder. The foregoing indemnification shall not apply to any Claims to the extent caused by the negligence of PPDI.

8.3 Notice. In the event that either Party seeks indemnification under Sections 8.1 or 8.2, the Party seeking indemnification agrees to (i) promptly inform the other Party of the Third Party Claim, (ii) permit the other Party to assume direction and control of the defense or claims resulting therefrom (including the right to settle it at the sole discretion of that Party), and (iii) cooperate as reasonably requested (at the expense of that Party) in the defense of the Claim.

8.4 Insurance.

(a) Prior to the first human clinical trials of a Licensed Product under this Agreement, PPDI shall obtain and maintain broad form comprehensive general liability insurance and Licensed Products liability insurance with a reputable and financially secure insurance carrier, to cover such activities of PPDI and PPDI's contractual indemnity under this Agreement. Such insurance shall provide minimum annual limits of liability of $1,000,000.00 per occurrence and $3,000,000 in the aggregate with respect to all occurrences being indemnified under this Agreement. Such insurance policy shall be purchased and kept in force for the period of five (5) years after the cessation of sales of all Licensed Products under this Agreement.

(b) In the event that PPDI chooses to rely on any strategic partners of PPDI to satisfy any of the requirements for insurance under this Section 8.3, then PPDI shall provide details of such coverage to BDSI for its information. Any such coverage must substantially comply with the form, scope and amounts set forth in this Section 8.3(a) which are applicable to such insurance. In the event that any such insurance is a self-insured plan, PPDI shall determine that such strategic partner's self-insured plan is adequate given the financial condition of such strategic partner. At BDSI's request, which shall not be more frequently than annually, PPDI shall provide BDSI with a certificate of such insurance or written verification by such strategic partner of such self-insurance.

(c) At BDSI's request, which shall not be more frequently than annually, PPDI shall provide BDSI evidence of any insurance obtained pursuant to Section 8.3(a). PPDI shall not, and shall not permit any strategic partner to, cancel or materially reduce the coverage of any policy of insurance required under this Section 8.3(a) without giving BDSI thirty (30) days prior written notice thereof.

ARTICLE 9 - TERM; TERMINATION

9.1 Term. This Agreement shall commence as of the Effective Date and, unless sooner terminated as provided hereunder, shall terminate as to each Licensed Product and as to each country in the Territory, upon the expiration of the last to expire Valid Claim of a Licensed Patent necessary for the manufacture, use or

sale of such Licensed Product in such country.

9.2 Breach. Failure by either Party to comply with any of the material obligations contained in this Agreement shall entitle the other Party to give to the Party in default notice specifying the nature of the default and requiring it to cure such default. If such default is not cured within sixty (60) days after the receipt of such notice (or, if such default cannot be cured within such sixty (60) day period, if the Party in default does not commence and diligently continue actions to cure such default), the notifying Party shall be entitled, without prejudice to any of its other rights conferred on it by this Agreement, in addition to any other remedies available to it by law or in equity, to terminate this Agreement by giving written notice to take effect within thirty (30) days after such notice unless the defaulting Party shall cure such default within said thirty (30) days. The right of either Party to terminate this Agreement, as hereinabove provided, shall not be affected in any way by its waiver or failure to take action with respect to any previous default.

9.3 Termination by PPDI. PPDI shall have the right to terminate the licenses granted herein, in whole or as to any Licensed Product in any country in the Territory, at any time, and from time to time, by giving notice in writing to BDSI. Such termination shall be effective thirty (30) days from the date such

notice is given, and all PPDI's rights associated therewith shall cease as of that date, subject to Section 9.4.

9.4 Rights to Sell Stock on Hand. Upon the termination of any license granted herein, in part or in whole or as to any Licensed Product, for any reason other than a failure to cure a material breach of the Agreement by PPDI, PPDI shall have the right for one (1) year or such longer period as the Parties may reasonably agree to dispose of all Components or substantially completed Components then on hand to which such termination applies, and Running Royalties shall be paid to BDSI with respect to such Components as though this Agreement had not terminated.

9.5 Termination of Sublicenses. Upon any termination of this Agreement, all sublicenses granted by PPDI under this Agreement shall terminate simultaneously, subject, nevertheless, to Section 9.4.

9.6 Effect of Termination. Upon the termination of any license granted herein as to any Licensed Product in any country in the Territory other than pursuant to Section 9.1, PPDI and its Affiliates and Sublicensees shall promptly: (i) return to BDSI all relevant records, materials or confidential information of BDSI concerning the Licensed Technology relating to such Licensed Product in such country in the possession or control of PPDI or any of its Affiliates or Sublicensees; and (ii) assign to BDSI, or BDSI's designee, its registrations with governmental health authorities, licensees, and approvals of such Licensed Product in such country.

9.7 Surviving Rights. Termination of this Agreement shall not terminate PPDI's obligation to pay all Running Royalties which shall have accrued hereunder. The Parties' obligations under Articles 7, 8 and 9 and Sections 11.6 and 11.10 shall survive termination.

9.8 Accrued Rights, Surviving Obligations. Termination, relinquishment or expiration of this Agreement for any reason shall be without prejudice to any rights which shall have accrued to the benefit of either Party under this Agreement prior to such termination, relinquishment or expiration. Such termination, relinquishment or expiration shall not relieve either Party from obligations which are expressly indicated to survive termination or expiration of this Agreement.

ARTICLE 10 - SUPPLIES OF MATERIAL

10.1 BDSI Supply Requirements. ***. CONFIDENTIAL TREATMENT REQUESTED

10.2 Assistance in Third Party Contractor Identification. In the event that BDSI desires to use a Third Party contractor for supply of cochleates, cochleate derivatives, proteoliposomes or Component Product, BDSI shall obtain PPDI's prior written approval for use of such Third Party contractor, the approval of which shall not be unreasonably withheld.

ARTICLE 11 - MISCELLANEOUS PROVISIONS

11.1 Relationship of Parties. Nothing in this Agreement is or shall be deemed to constitute a partnership, agency, employee or joint venture relationship between the Parties. No Party shall incur any debts or make any commitments for the other, except to the extent, if at all, specifically provided herein.

11.2 Assignment. Except as otherwise provided herein, neither this Agreement nor any interest hereunder shall be assignable by any Party without the prior

written consent of the other; provided, however, that either Party may assign this Agreement to any wholly-owned subsidiary or to any successor by merger or sale of substantially all of its assets to which this Agreement relates in a manner such that the assignor shall remain liable and responsible for the performance and observance of all its duties and obligations hereunder. This Agreement shall be binding upon the successors and permitted assigns of the parties and the name of a Party appearing herein shall be deemed to include the names of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment not in accordance with this Section 10.2 shall be void.

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

11.4 Force Majeure. Neither Party shall be liable to the other for loss or damages nor shall have any right to terminate this Agreement for any default or delay attributable to any act of God, flood, fire, explosion, strike, lockout, labor dispute, shortage of raw materials, casualty, accident, war, revolution, civil commotion, act of public enemies, blockage or embargo, injunction, law, order, proclamation, regulation, ordinance, demand or requirement of any government or subdivision, authority or representative of any such government, or any other cause beyond the reasonable control of such Party, if the Party affected shall give prompt notice of any such cause to the other Party. The Party giving such notice shall thereupon be excused from such of its obligations hereunder as it is thereby disabled from performing for so long as it is so disabled and for thirty (30) days thereafter. Notwithstanding the foregoing, nothing in this Section 10.4 shall excuse or suspend the obligation to make any payment due hereunder in the manner and at the time provided.

11.5 No Trademark Rights. Except as otherwise provided herein, no right, express or implied, is granted by this Agreement to use in any manner the name "PPDI" or "BDSI" or any other trade name or trademark of the other party in connection with the performance of this Agreement.

11.6 Public Announcements. Except as required by law, neither Party shall make any public announcement concerning this Agreement or the subject matter hereof without the prior written consent of the other. In the event of a required public announcement, the Party making such announcement shall provide the other with a copy of the proposed text prior to such announcement.

11.7 Notices. Any notice required or permitted to be given or delivered

hereunder or by reason of the provisions of this Agreement shall be in writing and shall be deemed to have been properly served if: (a) delivered personally, (b) delivered by a recognized overnight courier service instructed to provide next-day delivery, (c) sent by certified or registered mail, return receipt requested and first class postage prepaid, or (d) sent by facsimile transmission followed by confirmation copy delivered by a recognized overnight courier service the next day. Such notices, demands and other communications shall be sent to the addresses set forth below, or to such other addresses or to the attention of such other person as the recipient Party has specified by prior written notice to the sending Party. Date of service of such notice shall be: (i) the date such notice is personally delivered or sent by facsimile transmission (with issuance by the transmitting machine of confirmation of successful transmission), (ii) three days after the date of mailing if sent by certified or registered mail, or (iii) one day after date of delivery to the overnight courier if sent by overnight courier. Unless otherwise specified in writing, the mailing addresses of the Parties shall be as described below:

(a) If to BDSI, addressed to:

BioDelivery Sciences International, Inc.
185 South Orange Avenue, Administrative Building No. 4,
Newark, NJ 07103
Telephone No.:
Fax No.:

with a copy to the following:

Ellenoff Grossman Schole & Cyruli, LLP
370 Lexington Avenue
New York, NY 10017
Telephone No.: (212) 370-1300
Fax No.: (212) 370-7889

Attn: Barry I. Grossman, Esq.
Douglas S. Ellenoff, Esq.

(b) If to PPDI, addressed to:

Pharmaceutical Product Development, Inc.
3151 South Seventeenth Street
Wilmington, NC 28412
Attn: Chief Executive Officer
Telephone No.: 910-772-6881
Fax No.: 910-343-5920

with a copy to each of the following:
General Counsel
3151 South Seventeenth Street
Wilmington, NC 28412
Telephone No.: 910-772-6829
Fax No.: 910-772-6951

11.8 Amendment. No amendment, modification or supplement of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party. This Agreement may be executed in a series of counterparts, all of which, when taken together, shall constitute one and the same instrument.

11.9 Waiver. No provision of this Agreement shall be waived by any act, omission or knowledge of a Party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by the waiving Party.

11.10 Governing Law. This Agreement shall be governed by and interpreted in accordance with the laws of the State of orth Carolina.

11.11 Severability. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be prohibited by or invalid under applicable law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement.

11.12 Entire Agreement of the Parties. This Agreement constitutes and contains the entire understanding and agreement of the Parties and cancels and supersedes any and all prior negotiations, correspondence, understandings and agreements, whether oral or written, between the Parties respecting the subject matter hereof.

[NEXT PAGE IS THE SIGNATURE PAGE]

IN WITNESS WHEREOF, each of the Parties has caused this Agreement to be executed by its duly authorized officer as of the day and year first above written.

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ Francis E. O'Donnell, Jr

Name: Francis E. O'Donnell, Jr., M.D.
Title: President and CEO

PHARMACEUTICAL PRODUCT DEVELOPMENT, INC.

By: /s/ Fred N. Eshelman

Name: Fred N. Eshelman
Title: Vice Chairman and CEO

EXHIBIT A

EVALUATION AGREEMENT

EXHIBIT B

LICENSED PATENTS

United States Patent Number 4,663,161, entitled "Liposome Methods and Compositions", issued May 5, 1987

United States Patent Number 4,871,488, entitled "ReconstitutingViral Glycoproteins Into Large Phospholipids Vesicles, issued October 3, 1989

United States Patent Number 5,643,574, entitled "Protein- or Peptide- Cochleate Immunotherapeutics and Methods of Immunizing Using the Same", issued July 1, 1997.

United States Patent Number 5,834,015, entitled "Protein-lipid Vesicles and Autogenous Immunotherapeutic Comprising the Same", issued November 10, 1998.

United States Patent Number 5,840,707, entitled "Stabilizing and Delivery Means of Biological Molecules", issued November 24, 1998.

United States Patent Number 5,994,318, entitled "New cochleate formulations, useful for the delivery of biologically relevant molecules e.g. nutrients, lipophilic drugs and enzymes", issued November 30, 1999.

United States Patent Number 6,153,217, entitled "New lipid-based cochleates formed using a mixture of 2 polymers, useful for the delivery of e.g. drugs, polynucleotides, polypeptides or antigens", issued November 28, 2000.

United States Patent Number 6,165,502, entitled "Protein-lipid Vesicles and Autogenous Immunotherapeutic Comprising the Same", issued December 26, 2000.

United States Patent Application Serial Number 08/130,986, filed October 4, 1993, corresponding to PCT Application No. PCT/US94/10913, filed September 30, 1994.

United States Patent Application Serial Number 08/394,70, filed February 22, 1995, corresponding to PCT Application No. PCT _____, filed _____.

European Patent No. EP 0722338, entitled "Protein- and Peptide Cochleate Vaccines Methods of Immunizing Using the Same", granted July 25, 2001.

Australian Patent No. 722647, entitled "Protein-lipid Vesicles and Autogenous Immunotherapeutic Comprising the Same", granted November 23, 2000.

Australian Patent No. 689505, entitled "Protein- or Peptide- Cochleate Immunotherapeutics and Methods of Immunizing Using the Same", granted February 2, 1998

PCT Patent Publication No. WO 200042989, entitled "New lipid-based cochleates formed using a mixture of 2 polymers, useful for the delivery of e.g. drugs, polynucleotides, polypeptides or antigens"

European Patent Application No. EP 1143933, entitled "New lipid-based cochleates formed using a mixture of 2 polymers, useful for the delivery of e.g. drugs, polynucleotides, polypeptides or antigens"

Australian Patent Application No. 200032133, entitled "New lipid-based cochleates formed using a mixture of 2 polymers, useful for the delivery of e.g. drugs, polynucleotides, polypeptides or antigens"

PCT Patent Publication No. WO 200152817, entitled "Cochleate composition useful in preparation of a nutrient or flavor substance comprises biologically relevant molecule, a negatively charged first lipid and a divalent cation or higher valent cation"

Australian Patent Application No. 200131114, entitled "Cochleate composition useful in preparation of a nutrient or flavor substance comprises biologically relevant molecule, a negatively charged first lipid and a divalent cation or higher valent cation"

PCT Patent Publication No. WO 9730725, entitled "New cochleate formulations, useful for the delivery of biologically relevant molecules e.g. nutrients, lipophilic drugs and enzymes"

Canadian Patent Application No. 2246754, entitled "New cochleate formulations, useful for the delivery of biologically relevant molecules e.g. nutrients, lipophilic drugs and enzymes"

EXHIBIT C

LICENSED TECHNOLOGY

I. COCHLEATE TECHNOLOGY

Origin of cochleates
Over the years, biochemists and biophysicists have studied artificial membrane systems to understand their properties and potential applications. In studying this topic, Demetrios Papahadjopoulos and coworkers began investigating the interactions of divalent cations with negatively charged lipid bilayers. They reported that the addition of calcium ions to small phosphatidylserine vesicles induced their collapse into discs which fused into large sheets of lipid. In order to minimize their interaction with water, these lipid sheets rolled up into jellyroll-like structures, termed "cochleate" cylinders, after the Greek name for a snail with spiral shell.

The Cochleate Advantage
Cochleate delivery vehicles represent a new technology platform for oral and systemic delivery of clinically important drugs that possess poor bioavailability. For example, oral cochleates have been successfully used in animal models for the delivery of drugs that previously were only available given by injection.

High stability: Cochleate delivery vehicles are stable phospholipids-divalent cation precipitates composed of simple, naturally occurring materials, for example, phosphatidylserine and calcium. They have a unique multilayered structure consisting of a large, continuous, solid, lipid bilayer sheet rolled up in a spiral, with no internal aqueous space. Cochleates can be stored in a cation-containing buffer, or lyophilized to a powder and stored at room temperature. Lyophilized cochleates can be placed in capsules and given orally, or reconstituted with liquid prior to in vitro use or in vivo administration. Lyophilization has no adverse effects on cochleate morphology or functions. Cochleate preparations have been shown to be stable for more than two years at 4(degree)C in a cation-containing buffer, and at least one year as a lyophilized powder at room temperature. Encochleation imparts increased stability to drugs,

proteins and polynucleotides.

Encapsulation: Cochleate delivery vehicles "wrap-up" or encapsulate the drug, rather than chemically bond with the included drug.

Target delivery: Cochleates carry the encapsulated drug within the interior of the formulation and delivery the drug to the target cell. This results in low blood levels of free drug and high efficiency delivery to the target cell. Once at the target cell, cochleates can be envisioned as membrane fusion intermediates. When a cochleate comes into close approximation to a target membrane, a fusion event between the outer layer of the cochleate and the cell membrane occurs. This fusion results in the delivery of a small amount of the encochleated material into the cytoplasm of the target cell. The cochleate may slowly fuse or break free of the cell and be available for another fusion event, either with this or another cell. Cochleates may also be taken up by endocytosis, and fuse from within endocytic vesicles.

Resistance to environmental attack: The unique structure of the cochleate provides protection from degradation for associated "encochleated" molecules. Traditionally, many drugs can be damaged from exposure to adverse environmental conditions such as sunlight, oxygen, water and temperature. Since the entire

cochleate structure is a series of solid layers, components within the interior of the cochleate structure remain intact, even though the outer layers of the cochleate may be exposed to harsh environmental conditions or enzymes.

Oral availability: The drug delivery technology is being developed to enable oral availability of a broad spectrum of compounds, such as those with poor water solubility, as well as polynucleotides, and protein and peptide biopharmaceuticals, which have been difficult to formulate and administer.

Release characteristics: The cochleate technology offers the potential to be tailored to control the release of the drug depending on the desired application.

Formulation of Cochleates

BDSI scientists have investigated various aspects of the manufacturing process, including pH, agitation method and rate, type of cation, ratio of lipid to material, and other parameters, in order to optimize the formulation and manufacturing process for a given material. In one typical manufacturing process, the materials to be formulated (chemical drugs, proteins, peptides, DNA, antigens, nutrients) are added to a suspension of liposomes comprised mainly of negatively charged lipids. The addition of divalent metal ions such as calcium, (although other multivalent cations can be used) induces the collapse and fusion of the liposomes into large sheets composed of lipid bilayers, which spontaneously roll up or stack into cochleates. If desired, the cochleates can be purified to remove unencochleated material, and then resuspended in a buffer containing divalent metal ions.

Various processes have been developed by BDSI scientists to prepare cochleate formulations of a wide variety of drugs, peptides and proteins, with molecular weights ranging from 1 to greater than 200KD, and oligonucleotides or DNA of 20 to greater than 10,000 base pairs. The percentage of encochleation of material ranges from 40-95%, depending on the material and the manufacturing conditions.

Biocompatibility of Cochleate Vehicles

The fundamental components of the cochleate delivery vehicle are phosphatidylserine (PS) and calcium. Phosphatidylserine is a natural component of all biologic membranes, and is most concentrated in the brain. Clinical studies by other investigators, (more than 30 have been published), to evaluate the potential of phosphatidylserine as a nutrient supplement indicate that PS is very safe and may play a role in the support of mental functions in the aging brain. Indeed, phosphatidylserine isolated from soy beans is sold in health food stores as a nutritional supplement.

In mice, BDSI has evaluated the in vivo safety of multiple administrations of cochleates by various routes, including intravenous, intraperitoneal, intranasal and oral. Multiple administrations of cochleate formulations to the same animal do not result in either the development of an immune response to the cochleate matrix, or to any side effects relating to the cochleate vehicle.

Mechanism of Delivery
The interaction of calcium with negatively charged lipids has been extensively studied. Many naturally occurring membrane fusion events involve the interaction of calcium with negatively charged phospholipids (generally phosphatidylserine and phosphatidylglycerol). Calcium induced perturbations of membranes containing negatively charged lipids, and the subsequent membrane fusion events, are important mechanisms in many natural membrane fusion processes. Hence, cochleates can be envisioned as membrane fusion intermediates.

During the past several years substantial research by BDSI scientists has demonstrated that cochleate formulations are simple, safe and highly efficacious mediators of the in vivo delivery of proteins, peptides and polynucleotides for the induction of antigen specific immune responses following oral, intranasal and intramuscular administration. Significantly, the ability of cochleates to mediate the induction of antigen specific, CD8+ cytotoxic lymphocytes, as well as the efficient induction of immune responses to plasmid encoded antigens, supports the hypothesis that cochleates facilitate the cytoplasmic delivery of cochleate associated bioactive molecules.

The observations indicate that, as the calcium rich, highly ordered membrane of a cochleate first comes into close approximation to a natural membrane, a perturbation and reordering of the cell membrane is induced. This results in a fusion event between the outer layer of the cochleate and the cell membrane. This fusion also results in the delivery of a small amount of the encochleated material into the cytoplasm of the target cell. The cochleate may slowly fuse or break free of the cell and be available for another fusion event, either with this or another cell. Cochleates may also be taken up by endocytosis, and fuse from within endocytic vesicles.

Uptake of Cochleates by Macrophage
An important observation relative to the interaction of cochleates with cells is their uptake by macrophage. For example, in vivo, fluorescent cochleates are accumulated by macrophage. Macrophages are on the first line of defense against microbial infections. Many human pathogens cause diseases because they have developed the capacity to survive within macrophage. Examples include viruses such as HIV, bacteria such as staphylococcus and Mycobacterium tuberculosis, fungi such as Candida and parasites such as Leishmania.

Cochleate Mediated Oral Delivery of Drugs
Cochleate formulation technology is particularly applicable to macromolecules as well as small molecule drugs that are hydrophobic, positively, or negatively charged, and possess poor oral bioavailability. Proof-of-principle studies for cochleate mediated oral delivery of macromolecules as well as small molecule drugs is being carried out in appropriate animal models with a well established, clinically important drug which currently can only be effectively delivered by injection, amphotericin B, a potent antifungal agent.

II. PROTEOLIPOSOME TECHNOLOGY

Proteoliposome Technology (PLT), relates to novel liposome compositions and methods for their preparation. Utilization of PLT provides an efficient reconstitution of membrane proteins into large (0.1 to 2 micron diameter) phospholipid vesicles with a large, internal aqueous space. The method has been exemplified with the use of glycoproteins of influenza (A/PR8/34) and Sendai (parainfluenza type I) viruses. The method comprises (A) extracting out the desired membrane protein from a source biological material with an extraction buffer comprising a detergent; (B) mixing the extract with a phospholipid solution and deriving a cochleate intermediate; and (C) forming large phospholipid vesicles with integrated membrane protein in a biologically active state.

PLT has been used to produce liposome structures with improved delivery capabilities for drug delivery and gene therapy as well as enhanced immune responses. In addition, BDSI PLT can be used to formulate and stabilize biologically important but structurally fragile hydrophobic proteins.
The PLT is protected by US Patent Nos. 4,663,161 and 4,871,488.

EXHIBIT 99.1

For Release: IMMEDIATELY

Contact: Raphael Mannino, Ph.D.	Susan Bonitz, Ph.D.	Kevin Nally
Executive V.P., CSO	Pharmaceutical	L.G. Zangani LLC
BioDelivery Sciences	Business Development	(908) 788-9660
(973) 972-0015	L.G. Zangani LLC	
	(908) 788-9660	

NEWS RELEASE

BioDelivery Sciences International
Announces Licensing Agreement with PPD

NEWARK, N.J. (January 6, 2003) - BioDelivery Sciences International, Inc. (Nasdaq: BDSI, BDSIW) today announced it has signed a license agreement with PPD, Inc. (Nasdaq: PPDI).

Under the terms of the agreement, BioDelivery Sciences International granted PPD the right to apply BDSI's bioral nano-delivery technology to two therapeutic products. The BDSI technology can be used by PPD to encapsulate the therapeutic products to enable oral delivery without the need for further chemical modification.

BioDelivery Sciences International will receive a one-time upfront license fee, milestone payments based on certain regulatory filings and approvals, and royalties based on worldwide sales.

Separately, BioDelivery Sciences International has also entered into a confidential evaluation agreement with a major pharmaceutical company for encochleation of a proprietary antimicrobial. BDSI will be paid for its services related to the evaluation. In exchange, the pharmaceutical company has an exclusive option to negotiate a license for application of the Bioral(TM) delivery technology to its antimicrobial pharmaceutical.

BioDelivery Sciences International is a developmental-stage biotechnology company that is developing and seeking to commercialize a patented delivery technology designed for a potentially broad base of pharmaceuticals, vaccines, over-the-counter drugs, nutraceuticals and micronutrients in processed foods and beverages. For more information on BDSI, visit our Web site at http://www.biodeliverysciences.com.

As a leading global provider of discovery and development services and products for pharmaceutical and biotechnology companies, PPD applies innovative technologies, therapeutic expertise and a commitment to quality to help clients maximize the return on their R&D investments. With proven early discovery through post-market resources, the company also offers unique partnerships and alliances for virtual drug development. PPD has more than 5,200 professionals in 24 countries around the world. For more information on PPD, visit our Web site at http://www.ppdi.com.

Note: Except for the historical information contained herein, this press release contains forward-looking statements that involve risks and uncertainties. Such statements are subject to certain factors, which may cause the company's results to differ. Factors that may cause such differences include, but are not limited to, the company's ability to accurately forecast the demand for each of their products, the gross margins achieved from the sale of those products and the expenses and other cash needs for the upcoming periods, the company's ability to obtain finished goods from its contract manufacturers on a timely basis if at all, the company's need for additional funding, uncertainties regarding the company's intellectual property and other research, development, marketing and regulatory risks and certain other factors that may affect future operating results and are detailed in the company's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission.

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