

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

FORM 8-K

CURRENT REPORT

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

October 3, 2003
Date of Report (Date of earliest event reported)

Discovery Laboratories, Inc.
(Exact name of Registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)	000-26422 (Commission File Number)	94-3171943 (IRS Employer Identification Number)
---------------------------------------------------------------	---------------------------------------	-------------------------------------------------------

350 Main Street, Suite 307
Doylestown, Pennsylvania 18901
(Address of principal executive offices)

(215) 340-4699
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Item 5. Other Events and Regulation FD Disclosure

In connection with the transfer by Discovery Laboratories, Inc. (the "Company"), of its Surfaxin(R) manufacturing facilities from Akorn, Inc. ("Akorn"), the Company has entered into a Technology Transfer and Manufacturing Agreement (the "Agreement") with Laureate Pharma, L.P. ("Laureate"), which is attached hereto as Exhibit 10.1. The Agreement contemplates the transfer of the Company's Surfaxin manufacturing line, which previously existed at Akorn, to Laureate's manufacturing facilities in Totowa, New Jersey, and the further installation, validation and start-up of the Surfaxin manufacturing line at Laureate's manufacturing facilities. The transfer has already been completed. In addition, the Agreement contemplates the installation, validation and start-up of a new Surfaxin manufacturing and filling line to produce large-scale commercial and clinical supplies of Surfaxin.

Item 7. Financial Statements, Pro Forma Financial Statements and Exhibits

(c) Exhibits:

10.1 Technology Transfer and Manufacturing Agreement (as defined in Item 5 above).

Confidential treatment has been requested with respect to certain portions of the exhibit. Such portions have been separately filed with the Securities and Exchange Commission and redacted herein.

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.

Discovery Laboratories, Inc.

By: /s/ Robert J. Capetola

Name: Robert J. Capetola, Ph.D.

Title: President and
Chief Executive Officer

Date: October 22, 2003

Portions of this Exhibit have been omitted pursuant to a request for confidential treatment. The omitted portions, marked by [***], have been separately filed with the Securities and Exchange Commission.

TECHNOLOGY TRANSFER AND MANUFACTURING AGREEMENT

This TECHNOLOGY TRANSFER AND MANUFACTURING AGREEMENT, effective as of this 3rd day of October 2003 (the "Effective Date"), between DISCOVERY LABORATORIES, INC., a Delaware corporation ("Discovery"), having its principal place of business at 350 South Main Street, Suite 307, Doylestown, PA 18901, and LAUREATE PHARMA, L.P., a Delaware limited partnership ("Laureate"), having a principal place of business at 201 College Road East, Princeton, NJ 08540, (each a "Party", collectively the "Parties").

W I T N E S S E T H:

WHEREAS, Laureate possesses capabilities relating to the manufacture of sterile pharmaceutical products.

WHEREAS, Laureate provides a full range of processing services to the pharmaceutical industry, including process development, bioanalytical chemistry, microparticle production, formulation, aseptic filling and Quality Control testing.

WHEREAS, Discovery desires Laureate to perform services in accordance with the terms of this Agreement and the Scope (as hereinafter defined) related to the scale up, validation and manufacture of SurfaxinTM clinical and commercial supplies, and Laureate desires to perform such services.

NOW, THEREFORE, in consideration of the above statements and other good and valuable consideration, the sufficiency and receipt of which are hereby acknowledged, the Parties hereto agree as follows:

Section 1. Definitions. Terms defined elsewhere in this Agreement shall have the meanings set forth therein for all purposes of this Agreement unless otherwise specified to the contrary. The following terms shall have the meaning set forth below in this Section 1:

1.1 "Affiliate(s)" for purposes of this Agreement shall mean any Person, firm, trust, partnership, corporation, company or other entity or combination thereof which directly or indirectly: (i) controls a party; (ii) is controlled by a Party; or (iii) is under common control with a Party. As used in this definition, the terms "control" and "controlled" shall mean ownership of fifty percent (50%) or more (including ownership by trusts with substantially the same beneficial interests) of the voting and equity rights of such person, firm, trust, partnership, corporation, company or other entity or combination thereof or the power to direct the management of such person, firm, trust, corporation or other entity or combination thereof.

1.2 "Agreement" means this document as signed by the Parties including the Scope and any referenced attachments and any amendments and additions to this document or such attachments.

1.3 "Assumptions" shall have the meaning as set forth in Section 9.

TECHNOLOGY TRANSFER AND MANUFACTURING AGREEMENT

1

1.4 "Batch" means formulated Drug Product yielding a quantity of bulk volume and/or vials manufactured at the same time and identified by a unique lot number.

1.5 "Batch Record" means all associated documentation utilized for manufacturing a Batch generated by Laureate and approved by Discovery made concurrently with the performance of each step of the manufacturing process for the Drug Product, such that successive steps in such processes may be traced.

1.6 "Claim" shall have the meaning set forth in Section 19(a).

1.7 "Contaminants" shall have the meaning set forth in Section 19(c).

1.8 "Discovery Confidential Information" means any and all Discovery proprietary information concerning the Drug Substance or Drug Product previously not known to Laureate and supplied by Discovery to Laureate, and related processes, technologies, compounds, inventions, Discovery Know-How show-how, designs,

specifications, formulas, methods, samples, biological, chemical or other materials, medical or other devices, developmental or experimental work, improvements, discoveries, research and clinical or other data, databases, software, manuals, internal policies and procedures, patent applications, licenses, term sheets, prices, costs, financial information, budgets, projections, marketing, and selling and business plans, provided that such information is not developed jointly with Laureate or its employees or other personnel.

1.9 "Discovery Know How" means all scientific, technical and other information relating to the Drug Substance or Drug Product known to Discovery from time-to-time other than Laureate Confidential Information.

1.10 "Drug Product" means the final formulated dosage form pharmaceutical medicine containing Drug Substance and Other Active Ingredients, manufactured in accordance with cGMP and conforming to Specifications, that Discovery or its Affiliates will use for clinical trials and commercialization requirements.

1.11 "Drug Substance" means the Surfaxin peptide otherwise known as KL4 or sinapultide) in unformulated bulk form, to be supplied by Discovery's Third-Party raw material suppliers, manufactured in accordance with cGMP and conforming to Specifications.

1.12 "Excipients" means those inactive ingredients presently used in the Process that are not intended to exert therapeutic effects (i.e., [***])."

1.13 "Facility" or "Facilities" means either or both, as the case may be, of Laureate's manufacturing facilities located at 201 College Road East, Princeton, NJ 08540 or 710 Union Boulevard, Totowa, NJ 07512.

1.14 "FDA" shall mean the United States Food and Drug Administration.

1.15 "Filling Components" means vials, stoppers and crimps (overseals) used for an aseptic fill of the Drug Product.

Information marked by [***] has been omitted pursuant to a request for confidential treatment. The omitted portion has been separately filed with the Securities and Exchange Commission.

TECHNOLOGY TRANSFER AND MANUFACTURING AGREEMENT

1.16 "Filled Product" means vials filled with Drug Product from an identified Lot or Lots that are in a form ready for release and shipment from the Facility.

1.17 "Good Manufacturing Practices" or "GMP" or "cGMP" means current good manufacturing practices, as specified in regulations promulgated from time to time by the FDA for the manufacture and testing of pharmaceutical products. Laureate's operational quality standards are defined in internal cGMP policy documents and are based on Laureate's current interpretation of cGMP.

1.18 "Laureate Confidential Information" means any information, business, technical or financial data concerning Laureate's manufacturing processes and techniques including without limitation, Laureate Know How, previously not known to Discovery and related processes, technologies, compounds, inventions, Laureate Know-How, show-how, designs, specifications, formulas, methods, samples, biological, chemical or other materials, medical or other devices, developmental or experimental work, improvements, discoveries, research and clinical or other data, databases, software, manuals, internal policies and procedures, patent applications, licenses, term sheets, prices, costs, financial information, budgets, projections, marketing, and selling and business plans provided that such information is not developed jointly with Discovery or its employees.

1.19 "Laureate Group" shall have the meaning set forth in Section 19(b).

1.20 "Laureate Know How" means all scientific, technical and other information relating to the Process known to Laureate from time-to-time, other than Discovery Confidential Information, and including any such information generated as a result of performing the Program provided that such information is not developed jointly with Discovery or its employees.

1.21 "Laureate Process Inventions" means any patentable or otherwise protectable invention relating to the Process that is discovered by Laureate and results from Laureate's day-to-day contract manufacturing or other activities that are not directly related to the manufacture of Drug Product and/or the conduct of the Program; provided that such inventions are not developed jointly with Discovery.

1.22 "Laureate SOP" means the written standard operating procedures and methods of Laureate and any procedures provided by Discovery (once such procedures are accepted into the Laureate SOP system) that are specific to the Process as the same may be amended from time to time; provided, however, that any such amendments shall be promptly provided to Discovery.

1.23 "Loss" shall have the meaning set forth in Section 19.

1.24 "Lot" means the Drug Product produced in a single production, which may be delineated as a subplot if contained in one or more containers thereof.

1.25 "Materials" means raw materials, Drug Substance, Other Active Ingredients and excipients, Drug Product, reference standards and/or any other substances to be provided by Discovery to Laureate in order to undertake the Program as specified in the Scope and Appendix 1 to this Agreement.

1.26 "Modification" shall have the meaning set forth in Section 9.

TECHNOLOGY TRANSFER AND MANUFACTURING AGREEMENT

1.27 "Other Active Ingredients" means [***], to be supplied by Discovery's Third-Party suppliers, manufactured in accordance with cGMP and conforming to Specifications.

1.28 "Person" means an individual, partnership, corporation, limited liability company, joint stock company, unincorporated organization or association, trust or joint venture, or a governmental agency or political subdivision thereof.

1.29 "Process" means the manufacturing procedures used in connection with the manufacture of Drug Product including any improvements that may be made thereto from time-to-time.

1.30 "Process Consumables" means, filters, membranes, disposable analytical test kits, tubing, filling needles, disposable bags, disposable glass/plasticware, cleaning supplies and other changeover parts consumed during the manufacture of Drug Product.

1.31 "Process Equipment" means non-dedicated equipment that will be used by Laureate for the manufacture of Drug Substance or Drug Products pursuant to this Agreement as well as for other products for other customers.

1.32 "Product-Dedicated Equipment" means equipment such as vessels and formulation apparatus that will be used by Laureate solely for the manufacture of Drug Product pursuant to this Agreement.

1.33 "Product Invention" means any and all improvements, inventions (patentable or not), designs, ideas, works of authorship, copyrightable works, discoveries, trademarks, trade dresses, service marks, copyrights, trade secrets, formulas, processes, structures, product concepts, data, know-how, show-how, improvements, techniques, information or statistics contained in, or relating to, marketing plans, strategies, forecasts, blueprints, sketches, records, notes, devices, drawings, customer lists, patent applications, continuation applications, continuation-in-part applications, file wrapper continuation applications and divisional applications, all to the extent that they are exclusively related to Drug Product, discovered, made, conceived or reduced to practice by Laureate employees or its other personnel either solely or jointly with Discovery employees or its other personnel exclusively as a result of performing the Program pursuant to this Agreement.

1.34 "Program" means the services to be performed by Laureate for Discovery in connection with the manufacture of Drug Product as described in the Scope or otherwise in connection with the performance of this Agreement, as such services may be modified from time-to-time by mutual agreement of the Parties.

1.35 "Quality Agreement" shall have the meaning set forth in Section 3(c).

1.36 "Scope" means the various development and manufacturing activities intended to provide for certain clinical and commercial supplies of Surfaxin to be manufactured by Laureate for Discovery as described in Section 2 of this Agreement and as otherwise, based on Laureate SOP.

Information marked by [***] has been omitted pursuant to a request for confidential treatment. The omitted portion has been separately filed with the Securities and Exchange Commission.

TECHNOLOGY TRANSFER AND MANUFACTURING AGREEMENT

1.37 "Specifications" means the requirements as agreed between the Parties, for tests, analysis, test procedures and acceptable test results with which Drug Product, raw materials (including Drug Substance, Process Consumables, Other Active Ingredients and Excipients) shall conform as set forth in the Quality Agreement entered into by the Parties, as such agreement may be amended from time-to-time.

1.38 "Third Party" shall mean any party other than Discovery, Laureate and their respective Affiliates.

Section 2. Scope of the Program.

(a) A detailed Scope shall be jointly prepared promptly upon the execution of this Agreement by Laureate and Discovery and agreed upon by both Parties and will become an attachment and integral part of this Agreement upon approval and consent to the Scope by the Parties. Upon such agreement and approval, Laureate shall perform the Program for Discovery in accordance with the Scope. The Scope will specify the Program design, information desired, estimated duration of the Program, and all other matters pertinent to completion of the Program; provided, however, that Laureate hereby acknowledges and agrees that the manufacturing relationship set forth in this Agreement shall be non-exclusive and that this Agreement shall not constitute an agreement between the Parties that Laureate shall be Discovery's sole or primary manufacturing facility; and further provided that Discovery hereby acknowledges and agrees that the manufacturing relationship set forth in this Agreement shall be nonexclusive and that this Agreement shall not constitute an Agreement between the parties that Discovery shall be Laureate's sole or primary customer in the Facility.

(b) The Parties acknowledge and agree that the overall objectives of the Program are to provide as quickly as reasonably practicable for the clinical and commercial production capability to manufacture Drug Product including, without limitation, by achieving the following Program milestones within the timeframes set forth below, unless otherwise mutually agreed to in good faith by the Parties:

(i) the successful installation, validation and start-up at Laureate's Facility of the Drug Product manufacturing line located previously at the manufacturing facility of Akorn, Inc. The Parties currently contemplate that the installation and setup of such manufacturing line at the Facility will be completed by September 30, 2003, in order to allow the production of stability Batches by November 30, 2003. As soon as practicable thereafter, sterility assurance of all support, utility, Facility and processing equipment will be qualified (contemplated to entail certain media Batches). A primary objective of this milestone shall be to enable production of a minimum of three clinical Lots by December 31, 2003; provided, however, that after production of the Initial Phase Batches (as such term is hereinafter defined), the Parties agree to conduct a good faith assessment of the conduct of the Program to date with the objective of determining a mutually agreeable basis for moving forward, with the production of such clinical Lots. Collectively, the stability Batches and media Batches referred to in this Section 2(b)(i) shall hereinafter be referred to as the "Initial Phase Batches"; and

(ii) the installation and qualification at Laureate's Facility, of a new filling line and new process equipment train capable of producing clinical and commercial Drug Product at an increased scale together with the filing of appropriate documentation for regulatory approvals, and scale-up to anticipated commercial requirements. The Parties currently contemplate that in accordance with the Program, as it may be modified from time-to-time, that such optimized Drug Product filling line and the manufacturing line will be qualified for use by March 31, 2004. In connection with the achievement of this milestone, the Parties contemplate the production of a number of stability, media and development Batches that collectively shall hereinafter be referred to as the "Development Phase Batches."

TECHNOLOGY TRANSFER AND MANUFACTURING AGREEMENT

(c) Laureate consulted and shall continue to consult with Discovery in developing the Program design in a manner consistent with Laureate's current reasonable understanding of United States (the "US") regulatory guidelines. Except as set forth herein, Laureate does not warrant that the Program and/or the Program results will satisfy the requirements of any regulatory agencies at the time of submission of Program results to such agencies and, further, it is acknowledged and agreed to by the Parties that should the Initial Phase Batches and or Development Phase Batches not be in compliance with the Specifications that such event shall not be subject to rejection pursuant to Section 16(d) or relieve Discovery of its payment obligations in accordance with Section 8 for such Batches.

(d) Laureate's performance of the Program will be based on technical information provided by or on behalf of Discovery. Such information will be incorporated by Laureate into Program documents (scale up plans, Batch Records, Specifications, etc.) that will be reviewed and approved by Discovery prior to use by Laureate. These documents will form the sole basis upon which the Program will be performed. Except as may be provided herein, Laureate makes no warranties that the execution of the Program according to the approved documents will result in any specific quantity or quality of Drug Product.

(e) In addition to routine Program meetings, senior representatives of the Parties shall meet on an occasional basis or as necessary, the first meeting being no later than one (1) month from the Effective Date, to review progress of the Program relative to the Scope and to agree on any necessary changes to the Scope. Any disagreement between the Parties concerning the Scope (including, without limitation, the failure of the Parties to agree upon any necessary changes to the Scope) shall be resolved in accordance with the dispute-resolution procedures set forth in Section 17 hereof.

Section 3. Program Performance.

(a) Discovery and Laureate are entering into a manufacturing and process development relationship with the purpose of manufacturing clinical and commercial supplies of Drug Product. Laureate shall use its commercially reasonable efforts to provide the Facility, supplies, staff and other resources necessary to complete the Program as provided in the Scope, as it may be modified as provided herein, in accordance with the terms of this Agreement. Discovery shall use its commercially reasonable efforts to provide the Drug Substance, Product Dedicated Equipment, Other Active Ingredient supplies, staff and other resources necessary to complete the Program as provided in the Scope, as it may be modified as provided herein, in accordance with the terms of this Agreement. In the event of any conflict between the terms and conditions of this Agreement and the Scope, the terms of this Agreement shall control.

(b) Laureate shall appoint a Laureate representative who shall be an employee of Laureate or its Affiliates (the "Program Manager"), to be responsible for the completion of the Program by Laureate. The Program Manager will coordinate performance of the Program with a representative designated by Discovery (the "Discovery Representative"), which representative shall have responsibility over all matters relating to the performance of the Program on behalf of Discovery. Unless otherwise agreed in the Scope, or mutually agreed to by the Parties in writing, all communications between Laureate and Discovery regarding the conduct of the Program pursuant to the Scope shall be addressed to or routed through the Program Manager and the Discovery Representative. Laureate may, at its option, substitute the Program Manager during the course of the Program. Discovery may, at its option, substitute the Discovery Representative during the course of the Program; provided, however that each Party hereby agrees to commit to the Program appropriate personnel (including, those with reasonably sufficient expertise in technical development, manufacturing, operations, quality control, quality assurance and regulatory affairs.)

TECHNOLOGY TRANSFER AND MANUFACTURING AGREEMENT

(c) As promptly as practicable following the Effective Date, the Parties will execute a detailed document ("Quality Agreement") specifying the quality and regulatory procedures and responsibilities of the Parties hereunder with respect to the manufacture of Drug Product.

Section 4. Program Equipment and Materials.

(a) The Parties acknowledge that (i) the initial phase of the Program (as described in Section 2(b)(i)) provides that Discovery, at its sole expense, shall arrange for the transfer to Laureate, installation and validation of its current manufacturing line now maintained at the facilities of Akorn; (ii) during the development phase of the Program (as described in Section 2(b)(ii)), certain equipment related to the scaled-up Drug Product manufacturing line, some of which is already specified and some of which may be specified in the future, must be obtained and installed and set-up and validated at the Facility at Discovery's sole expense, and (iii) upon mutual agreement, Laureate may make certain modifications to its Facility to provide for an expanded scale-up of production capacity for Drug Product; provided, that the costs of such modifications shall be allocated between the Parties as they may mutually agree in writing, with the final determination of any such allocation to be at the sole discretion of Laureate.

(b) Discovery will provide Laureate with [***] as required by Laureate to perform the Program as specified in the Scope and this Agreement, as well as all documentation and such other data as may be necessary to apprise Laureate of the stability of the Drug Substance, Other Active Ingredients and Drug Product and related process characteristics, proper storage, and manufacturing and safety requirements including, without limitation, Certificates of Analysis relating to the Drug Substance, Drug Product, Other Active Ingredients and reference standards as specified in Appendix 3; provided that all [***] shall be in compliance with the Specifications previously approved by Discovery. Any Product-Dedicated Equipment provided to Laureate by Discovery shall be clean, in good operating condition and free from all material defects.

(c) Laureate shall use commercially reasonable efforts to procure and maintain an adequate inventory of [***] for use in the Program and each manufacturing run based on Discovery's Purchase Orders; provided that all such materials shall be in compliance with the Specifications previously approved by Discovery. [***]

(d) Unless otherwise agreed to by the Parties, it is understood that Discovery shall procure the Product-Dedicated Equipment as set forth in the Scope, at Discovery's sole expense. Discovery shall have the right to label such equipment with plates or other appropriate markings.

(e) Upon completion of the Program: (i) the [***] will be returned to Discovery "as is" and "where is" in accordance with Discovery's written instruction related thereto, and at Discovery's expense; and (ii) any remaining [***] provided to Laureate will be returned to Discovery or retained by Laureate in compliance with applicable regulatory requirements or destroyed/disposed of by Laureate under written authorization from Discovery; provided, however that such instructions and authorizations shall be communicated by Discovery within thirty (30) of completion of the Program.

Information marked by [***] has been omitted pursuant to a request for confidential treatment. The omitted portion has been separately filed with the Securities and Exchange Commission.

TECHNOLOGY TRANSFER AND MANUFACTURING AGREEMENT

Section 5. Use of Subcontractors.

(a) Laureate shall have the right to employ subcontractors to undertake certain activities related to the Program; provided, however, that all such subcontractors shall be pre-approved by Discovery in writing; and further, provided, that Laureate at its sole discretion may utilize: (i) temporary and contract employees in connection with the Program; (ii) contractors and vendors for general maintenance, repair and operation of the Facility; and (iii) contractors for regulatory and quality issues. A list of known and approved subcontractors is provided in Appendix 4 to this Agreement. Except as set forth in the immediately preceding sentence, Laureate shall not employ, engage or contract with a Third Party in connection with or any part of the Program unless: (i) Laureate provides Discovery with prior written notice of such subcontracting arrangement; (ii) Discovery has given its prior written consent, which consent shall not be unreasonably withheld or delayed (except that no such approval shall be required for the subcontractors listed on Appendix 4); and (iii) Discovery at its sole expense may audit Laureate's subcontractors' qualification criteria and review Laureate's subcontractor audits upon reasonable notice during regular business hours and no more frequently than once per annum. Laureate shall cause any and all subcontractors engaged by Laureate to carry out any aspect of the Program to be held under obligation of confidentiality substantially similar to the terms, conditions and limitations set forth in Section 10.

(b) Except for (i) Discovery's rejection remedies provided for pursuant to Section 16(d) and (ii) the acts of subcontractors who are employees or consultants of Affiliates of Laureate and perform services under this Agreement at the Facilities, Laureate will not be held responsible or liable for the performance of any pre-approved subcontractor used for the Program or for any costs, expenses, damage or loss of any nature, whether direct or consequential occasioned by such contractor's performance or failure to perform.

Section 6. Compliance with Government Regulations.

(a) Laureate shall perform the Program in accordance with the Scope. Laureate will also comply in all material respects with applicable government regulatory requirements concerning cGMP appropriate to the Program; provided, however, that in the event of a conflict in government regulations, Discovery will designate, in writing, which regulations shall be followed by Laureate in its performance of the Program and otherwise in a manner consistent with the terms of this Agreement and shall hold Laureate harmless for following such written designation.

(b) Should any applicable government regulatory requirements concerning cGMP and appropriate to the Program be changed, the Parties shall promptly notify each other of any material revision or amendments of or additions to cGMP and will confer with each other with respect to the best means to comply with such requirements. Laureate shall use its commercially reasonable efforts to comply in all material respects with the new requirements. The Parties will allocate any costs of implementing any such agreed changes on an equitable basis, with Laureate being responsible for costs of implementation of changes required generally for cGMP manufacture at the Facility that are not directly related to the manufacture of Drug Product and Discovery being responsible for all other costs. Should Laureate, at its sole discretion, decide not to comply with such new requirements, after using commercially reasonable efforts to so agree, Laureate will not be obligated to continue to perform the then existing Program and Discovery or Laureate shall be entitled to immediately terminate this Agreement, (notwithstanding Section 23(b)).

TECHNOLOGY TRANSFER AND MANUFACTURING AGREEMENT

Section 7. Facility Visits and Audits. With reasonable advance notice, Discovery's representatives (including its employees, directors, consultants and other subcontractors) may visit the Facility at appropriate times consistent with the Program to observe the progress of the Program or to audit the Program subject to the access limitations set forth in Appendix 5 to this Agreement. Laureate will not be held responsible or liable for the performance of any Third Party retained by Discovery to perform services related to the Program, including, without limitation, distributors, consultants and testing entities.

(a) Laureate shall have the right at reasonable business hours and to the greatest reasonable extent that may be provided by Discovery to audit any sites or laboratories used by Discovery (except for Discovery's contract manufacturers) or any Third Party engaged by Discovery directly in connection with the manufacture of any Materials, the Drug Product, Drug Substance and other materials provided by or on behalf of Discovery to Laureate.

Section 8. Compensation.

(a) Laureate shall be paid the development and service fees listed on Appendix 6 (the "Service Fees") to perform the services set forth on Appendix 6, which Service Fees shall be subject to modification in accordance with the provisions of Section 9 and as otherwise set forth in Sections 8(b) and 8(c).

(b) The Parties hereby acknowledge and agree to, upon completion of the Initial Phase and Development Phase of the Program, negotiate in best faith a mutually agreeable monthly facility access fee and commercial pricing in connection with the manufacture of the commercial Drug Product product by Laureate. It is currently contemplated that an increase in Discovery's requirements may occur, if at all, upon the attainment of certain development and commercialization milestones including, but not limited to, regulatory approval of Surfaxin for the treatment of Respiratory Distress Syndrome in infants and the successful completion of Discovery's ongoing Phase 2 clinical trial for the treatment of Acute Respiratory distress syndrome in adults.

(c) Discovery shall pay Laureate the Service Fees in accordance with the payment schedule set forth on Appendix 6. Laureate shall invoice Discovery for [***] purchased by Laureate in accordance with Section 4 with an administrative fee equal to [***] of Laureate's actual cost of such Process Equipment and Materials (limited to an aggregate of \$[***] of Process Equipment costs subject to such administrative fee) purchased for the Program added to such invoices. Payments are due thirty (30) days from the date of invoice, except that the payments of the Service Fees shall be due at the times indicated in accordance with the terms and conditions set forth in Appendix 6. Late payments are subject to an interest charge of one percent (1%) per month computed on a daily basis.

Section 9. Change Orders.

(a) The Program is subject to a number of specific and general Assumptions. The specific assumptions include but are not limited to the Scope and Program design and objectives, timing, budgetary requirements, Laureate's Facility utilization schedule, labor and facility usage, availability of equipment and Materials, capital expenditure requirements, if any, and other matters relating to the completion of the Program as set forth in the Scope (the "Program Assumptions"). Laureate also

Information marked by [***] has been omitted pursuant to a request for confidential treatment. The omitted portion has been separately filed with the Securities and Exchange Commission.

TECHNOLOGY TRANSFER AND MANUFACTURING AGREEMENT

assumes that Discovery will cooperate and meet its obligations under this Agreement and Scope in a timely manner, that no event outside the control of Laureate will occur, including, without limitation, the events described in Section 21, and that there are no changes to any applicable laws, rules or regulations that affect the Program (the foregoing assumptions together with the Program Assumptions, collectively, the "Assumptions"). In the event that any of the Assumptions require modification or the Program objectives cannot be achieved based on the Assumptions (each being, a "Modification") then the Scope may be amended as provided in Section 9b.

(b) In the event the need for a reasonable Modification is identified by the Discovery or by Laureate, the identifying Party shall notify the other Party in writing as soon as is reasonably possible. Laureate shall use reasonable efforts to provide the Discovery with a written change order containing an estimate of the required adjustments to the Service Fees, when practicable, within ten (10) business days of receiving or delivering such notice (the "Change Order"). Discovery shall use its best efforts to respond in writing to such Change Order promptly. If Discovery does not approve such Change Order and has not terminated this Agreement and the Program in accordance with Section 23 but desires the Program to be modified to take into account the Modification, then Discovery and Laureate shall use good faith commercially reasonable efforts to agree on a Change Order that is mutually acceptable. If practicable, Laureate may, in its discretion, continue to work on the Program but Laureate shall not be obligated to work on the Program during any such negotiations. Laureate shall not commence work with respect to a Change Order unless authorized by Discovery in writing. Any disagreement between the Parties concerning a Change Order (including, without limitation, the failure of the Parties to agree upon a mutually acceptable Change Order) shall be resolved in accordance with the dispute-resolution procedures set forth in Section 17.

Section 10. Confidential Information/Legal Proceedings.

(a) Laureate shall not disclose, without Discovery's prior written permission, Discovery Confidential Information unless such disclosure: (i) is to an Affiliate of Laureate that is under a similar obligation to keep such information confidential; (ii) is to a subcontractor that has been pre-approved by Discovery in accordance with the terms and conditions set forth in Section 5 and that is under a similar obligation to keep such information confidential; (iii) is or becomes publicly available other than as a result of a breach of this Agreement by Laureate; (iv) is disclosed by a Third Party which Laureate reasonably believes is entitled to disclose it without restriction; (v) is already known to Laureate as shown by its prior written records; (vi) can be established by competent evidence as independently developed by Laureate without the use of Discovery Confidential Information; or (vii) is required by any law, rule, regulation, order decision, decree, subpoena or other legal process to be disclosed. If such disclosure is requested by legal process, Laureate will make all reasonable efforts to notify Discovery of this request promptly prior to any disclosure to permit Discovery to oppose such disclosure by appropriate legal action.

(b) Discovery shall not disclose, without Laureate's prior written permission, Laureate Confidential Information unless such disclosure: (i) is to an Affiliate of Discovery that is under a similar obligation to keep such information confidential; (ii) is or becomes publicly available other than as a result of a breach of this Agreement by Discovery; (iii) is disclosed by a Third Party which Discovery reasonably believes is entitled to disclose it without restriction; (iv) is already known to Discovery as shown by its prior written records; (v) can be established by competent evidence as is independently developed by Discovery without the use of Laureate Confidential Information (including Laureate Know-How); or (vi) is required by any law, rule, regulation, order decision, decree, subpoena or other legal process to be disclosed. If such disclosure is requested by legal process, Discovery will make all reasonable

efforts to notify Laureate of this request promptly prior to any disclosure to permit Laureate to oppose such disclosure by appropriate legal action.

(c) Laureate will not transfer any Materials without Discovery's prior written permission to any Third Party other than a subcontractor that has been approved by Discovery in accordance with the terms and conditions set forth in Section 5.

(d) In the event that a recipient Party of any confidential information hereunder is requested or required (by oral questions, deposition, interrogatories, requests for information or documents, subpoena, civil investigative demand or other process) to disclose all or any part of any confidential information, such receiving Party shall provide the disclosing Party with prompt notice of such request or requirement so that the disclosing Party may seek an appropriate protective order or waive compliance with the provisions of this Agreement, as well as notice of the terms and circumstances surrounding such request or requirement. In such case, the Parties will consult with each other on the advisability of pursuing any such order or other legal action or available steps to resist or narrow such request or requirement and shall provide reasonable assistance to the disclosing Party in connection therewith. If, failing the entry of a protective order or the receipt of a waiver hereunder, the receiving Party is, in the opinion of counsel acceptable to the disclosing Party, legally compelled to disclose such confidential information, the receiving Party may disclose that portion of the confidential information which counsel advises the receiving Party that it is legally compelled to disclose. In any event, the receiving Party will not oppose action by the disclosing Party to obtain an appropriate protective order or other reliable assurance that confidential treatment will be accorded the disclosure of such information. The receiving Party shall cause its representatives and agents to comply with this Section 10(d).

(e) If Laureate shall be obliged to provide testimony or records regarding the Program in any legal or administrative proceeding, then Discovery shall reimburse Laureate for its reasonable out-of-pocket costs plus a reasonable hourly fee for its employees or representatives at Laureate's standard commercial rates.

Section 11. Work Product. All work outputs (e.g., reports) will be prepared on Laureate's standard format unless otherwise specified in the Scope.

Section 12. Inventions and Patents.

(a) With respect to Product Inventions which may arise hereunder, the following shall apply:

(i) Product Inventions made jointly by employees and other personnel of Discovery, and employees of Laureate and other personnel, or other parties under obligation to assign their inventions to Discovery or Laureate, shall be the joint property of Discovery and Laureate; provided, however, that each Party shall grant to the other Party a non-exclusive, paid-up worldwide perpetual license in a form satisfying to the other Party and its counsel to use such Product Invention solely with respect to such Party's (and its respective Affiliates) business activities and provided, further, that any such license of Product Inventions to Laureate shall absolutely restrict Laureate from using such Product Invention, directly or indirectly, in connection with the development or manufacture or production of any pulmonary surfactant competitive with that of Discovery and any such licensed invention shall not be sublicensed by either Party;

(ii) Product Inventions made solely by employees or other personnel of Discovery or other parties under obligation to assign their inventions to Discovery shall be the exclusive property of Discovery;

TECHNOLOGY TRANSFER AND MANUFACTURING AGREEMENT

provided, however, that Laureate shall have a non-exclusive, paid-up perpetual worldwide license to such Product Invention solely with respect to Laureate's (or its Affiliates) manufacturing activities and, provided, further, that any such license to Laureate (or its Affiliates) shall absolutely restrict Laureate (or its Affiliates) from using such Product Invention, directly or indirectly in connection with the development, manufacture or production of any pulmonary surfactant competitive with that of Discovery and such licensed invention shall not be sublicensed; and

(iii) Product Inventions or Laureate Process Inventions made solely by employees or other personnel of Laureate or other parties under obligation to assign their inventions to Laureate shall be the exclusive property of Laureate; provided, however, that Laureate shall grant to Discovery a non-exclusive, paid-up perpetual worldwide license to such Product Invention solely with respect to the use of such invention by Discovery with respect to Discovery's (or its Affiliates) business activities; and provided, further, that that any such license to Discovery (or its Affiliates) shall absolutely restrict Discovery (or its Affiliates) from using such Product Invention, directly or indirectly in connection with the development, manufacture or production of any product other than pulmonary surfactant products, and such licensed Product Invention shall not be sublicensed.

(b) At either Party's request and at such Party's expense, the other Party will execute or cause its personnel to execute, any and all applications, assignments or other instruments and give testimony which shall be necessary to apply for and obtain Letters of Patent of the U.S. or of any foreign country with respect to any Product Invention. In the event of such request, the parties agree and acknowledge that the requesting party shall compensate the other party at its standard commercial rate for the time devoted to such activities and reimburse it for all reasonable expenses incurred.

(c) Laureate shall (i) retain all rights to any inventions relating to manufacturing methods and processes including any production, purification and formulation, processing and aseptic filling process previously discovered or developed by Laureate and (ii) own all rights in and to any Laureate Process Inventions and all Laureate Know How.

(d) Discovery agrees and acknowledges that Laureate Process Inventions and Laureate Know How are vested in Laureate and that Discovery shall not at any time have any right, title, license or interest in or to Laureate Know How or Process Inventions or any other intellectual property rights relating to the Process for which Laureate shall have the legal right therefor.

(e) Subject to Sections 10 and 12(a), each Party shall have the right to utilize data generated during the course of the Program to support applications, assignments or other instruments necessary to apply for and obtain Letters of Patent of the U.S. or of any foreign country with respect to Product Inventions or Laureate Process Inventions. Each Party agrees to promptly notify the other of any such Product Invention and shall notify the other Party at least ninety (90) days in advance of such application.

Section 13. Independent Contractor. Laureate shall perform the Program as an independent contractor of Discovery and shall have complete and exclusive control over its Facility, equipment, employees and agents. Nothing in this Agreement or other arrangements for which it is made shall constitute Laureate, or anyone furnished or used by Laureate in the performance of the Program, as an agent, employee, joint venture, partner, or servant of Discovery. Laureate also agrees that it neither it nor its Affiliates or any of their employees have any rights to receive any employee benefits such as health insurance and accident insurance, sick leave or vacation as are in effect generally for employees of Discovery. Laureate shall not enter into any agreements or incur any obligations on behalf of Discovery nor commit Discovery in any other manner without prior written consent from a duly authorized officer or representative of Discovery.

TECHNOLOGY TRANSFER AND MANUFACTURING AGREEMENT

Section 14. Insurance. Laureate agrees to maintain a standard property insurance policy covering the Materials, Process Equipment, Process Consumables and Filling Components while under control and care of Laureate, during the performance of the Program. Discovery agrees to maintain a standard property insurance policy covering the Product Dedicated Equipment. Discovery shall also maintain general liability insurance including bodily injury, death and property damage in the amount of Two Million Dollars (US \$2,000,000) per occurrence and Ten Million Dollars (US \$10,000,000) in the aggregate including product liability coverage during all times when the Drug Product is being used clinically, and thereafter, covering the Drug Product and Materials or any harms caused by the Drug Product and Materials, and to name Laureate as an additional insured under such policy at no cost to Laureate. Discovery further agrees to provide Laureate with a Certificate(s) of Insurance issued to Discovery for an insurance policy or policies directed to the aforementioned insurance coverage, in which Laureate is named as an additional insured.

Section 15. Shipping. Laureate shall package for shipment Drug Product, samples or other Materials in accordance with Discovery's written instructions and at Discovery's expense. All shipments will be F.O.B the Facility and Discovery shall bear all packaging, shipping and insurance charges as set forth in Appendix 7. Delivery of Drug Product, samples or other materials by Laureate shall be deemed to have taken place upon delivery to carrier at the Facility. Title and risk of loss shall transfer to Discovery on transfer of Drug Product to carrier at the Facility. Laureate shall accept no liability or responsibility and risk associated with failure of Drug Product to meet Specifications once this transfer has occurred. Laureate shall retain representative samples of Drug Product for record keeping, testing and regulatory purposes.

Section 16. Forecasts/ Purchase Orders/ Rejection

(a) Forecasts. Discovery shall provide Laureate with a good faith written estimate of its expected requirements, on an annual and per quarter basis, for Drug Product, in accordance with the terms and conditions set forth below:

(i) Annual Forecasts. On April 1, 2004 with respect to the 6 month period beginning July 1, 2004, Discovery shall provide Laureate with a 6 month minimum forecast of the Batches of Drug Product required by Discovery, delineated to the greatest reasonable extent possible by month, for the following 6 months ("Initial Forecast"). Commencing October 1, 2004 with respect to the 12 month period beginning January 1, 2005 (and on the successive one year anniversaries of October 1, 2004, and with respect to succeeding 12 month periods), Discovery shall provide Laureate with a 12 month minimum forecast of the Batches of Drug Product required by Discovery, delineated to the greatest reasonable extent possible by quarter, for the following 12 months (collectively, the "Annual Period"). The Initial Forecast and all succeeding forecasts shall hereinafter be herein referred to the "Annual Commitment." Upon the expiration of each and every Annual Period, if Discovery shall have failed to purchase, in the aggregate, that number of Batches specified in the Annual Commitment, Discovery shall pay to Laureate, in accordance with the terms and conditions set forth in Section 8, an amount equal to 65% of the total Service Fees that would have been due with respect to that number of Batches that Discovery so failed to purchase during the applicable Annual Period. Laureate hereby acknowledges and agrees that the Annual Commitment amount shall be decreased by that amount of Batches, if any, that Laureate has failed to supply in accordance with Section 16(d) or that Discovery has obtained from a back-up supplier, solely in accordance with Section 16(e).

(ii) Quarterly Forecasts: Within seven (7) days following the Effective Date and not less than 10 days before the beginning of each calendar quarter thereafter, Discovery shall submit to Laureate, in writing, a non-binding forecast of the number of Batches the Customer reasonably believes it will

require for each Drug Product during the next 12 month period and the estimated timing for delivery of such Filled Product.

(b) Order Placement Procedure. Discovery shall submit binding Purchase Orders (each, a "Purchase Order" and collectively "Purchase Orders") in accordance with the terms and conditions set forth below. Such orders shall be set forth on Discovery's standard Purchase Order form, which, unless previously agreed upon in writing by Laureate, shall not be submitted to Laureate any less than thirty (30) days from the date such Batch is to be produced, specifying the quantity, concentration and container size of Drug Product ordered and the requested delivery date. Within seven (7) days following the Effective Date, Discovery shall submit to Laureate a written Purchase Order for Drug Product for the calendar quarter ending on December 31, 2003, such Purchase Order to specify the number of Batches of Drug Product and the requested delivery date of such (which shall in no event be less than thirty (30) days from receipt of such firm and binding Purchase Order). At least ten (10) days prior to the beginning of each future calendar quarter during the term of this Agreement, Discovery shall submit to Laureate a written Purchase Order for Drug Product for the upcoming calendar quarter, such purchase order to specify the number of Batches of Drug Product and the requested delivery date of each Batch. Laureate shall accept all Purchase Orders it is able to meet on commercially reasonable terms. Upon accepting each purchase order, Laureate shall use commercially reasonable efforts to assign a production time for the batch according to its customary procedures and based on the availability of Materials, Process Consumables and Filling Components.

(c) Amendments. The Parties further agree that if the foregoing forecasting, and/or ordering or inventory mechanisms set forth in Section 16 are determined by the Parties, in good faith cooperation and giving reasonable consideration to each Party's economic and business needs, to be inappropriate given the experience of the Parties and the then-existing manufacturing and supply circumstances regarding Drug Product hereunder, the Parties shall negotiate in good faith appropriate amendments to the applicable mechanisms in the supply procedures.

(d) Rejection. Except with respect to [***], Discovery may reject Drug Product delivered by Laureate for failure to comply with the Specifications by giving Laureate written notice, upon which the Parties will cooperate to determine whether rejection was necessary or justified as set forth in the Quality Agreement; provided, however that Laureate shall not be responsible if such rejection is due directly or indirectly to Materials provided by Discovery not meeting Specifications and Discovery shall provide notice of any such rejection to Laureate within 15 business days of delivery of the Batch Record for any such Batch. Laureate will notify Discovery promptly as to whether it accepts Discovery's basis for any rejection. If the Parties disagree in good faith whether the Batch did not comply with the Specifications, they will promptly submit a sample of such Batch and applicable documentation to a mutually acceptable independent Third Party laboratory. Such Third Party laboratory shall determine whether such Batch conforms with the Specifications, and such determination shall be final, binding and determinative as to whether Discovery's rejection of such Product batch was justified. The costs of all Third Party testing shall be shared equally by the Parties. If Discovery has given notice of rejection, at Discovery's request, Laureate shall use commercially reasonable efforts to replace such rejected Drug Product. If the Third Party tester rules that a rejected Batch meets the Specifications, Discovery shall be obligated to purchase such Batch, irrespective of whether Laureate has already replaced it at Discovery's sole cost and expense. If Laureate accepts

Information marked by [***] has been omitted pursuant to a request for confidential treatment. The omitted portion has been separately filed with the Securities and Exchange Commission.

TECHNOLOGY TRANSFER AND MANUFACTURING AGREEMENT

Discovery's basis for rejection or the Third Party tester rules that a rejected Batch did not meet the Specifications, Laureate will not charge Discovery for such Batch or for shipping, insurance or freight costs therefor; provided, should the reasons for the noncompliance of such Batch be due solely to Laureate's failure to materially comply with the Process or cGMP, Laureate shall grant to Discovery an offset against future Service Fees equal to the aggregate cost of Drug Substance and Other Active Ingredients, that were provided by Discovery at its sole cost and expense with respect to such rejected Batch.

(e) Resolution of Supply Problems. If Laureate determines that it will not be able to supply to Discovery a material amount of the most recent Purchase Orders and/or forecasts of orders for Drug Product submitted by Discovery in accordance with this Section 16, Laureate shall immediately notify Discovery in writing of such determination, which notice shall provide Discovery with the details on the extent of the expected shortfall of supply, the causes of such inability to supply and Laureate's proposed solution to the supply problem. Upon such notice of a supply problem, or in any event upon Laureate's failure to satisfy, within the delivery time frame specified by Discovery consistent with this Section, a portion of the Drug Product ordered by Discovery in compliance with this Agreement (provided that such supply problem or failure cannot be satisfied or addressed by Discovery's and Laureate's existing inventories for the Drug Product and will cause an interruption in the commercial or clinical supply of the Drug Product for more than thirty (30) days), Discovery and Laureate will immediately meet and work together, in good faith, to identify an appropriate resolution to the supply problem.

Section 17. Default. Except as otherwise provided herein, if Laureate is in default of its material obligations under this Agreement, then Discovery shall promptly notify Laureate in writing of any such default. Laureate shall have a period of forty-five (45) days from the date of receipt of such notice within which to cure such default; provided, that, if such default renders an aspect of the Program invalid, then Laureate shall, at Discovery's option, either; (i) repeat that aspect of the Program at Laureate's cost within a time period mutually agreed to by Laureate and Discovery or (ii) refund the Service Fees paid by Discovery for that aspect of the Program. If Laureate shall fail to cure such default within the specified cure period or repeat the Program, as the case may be, then this Agreement shall, at Discovery's option, immediately terminate. In the event of such termination, Laureate shall not in any way be liable to Discovery in an amount that, in the aggregate, exceeds the related Service Fees paid by Discovery for that specific aspect of the Program.

(a) If Discovery is in default of its material obligations under this Agreement, Laureate shall promptly notify Discovery in writing of any such default. Discovery shall have a period of forty-five (45) days from the date of receipt of such notice within which to cure such default; provided, that, if Discovery fails to cure such breach within the specified cure period, this Agreement shall, at Laureate's option, immediately terminate. Notwithstanding the cure period specified in the preceding sentence, if Discovery fails to make any payment to Laureate within the time period specified in Section 8 and/or Appendix 6 attached hereto, Laureate may, in its discretion, suspend performance of the Program until Laureate receives such outstanding payment; provided, however, that if Discovery fails to make any payment by sixty (60) days from when such payment was due, Laureate may immediately terminate this Agreement.

(b) EXCEPT AS OTHERWISE SET FORTH IN SECTION 19(C), UNDER NO CIRCUMSTANCES SHALL EITHER PARTY BE ENTITLED TO INCIDENTAL, INDIRECT, CONSEQUENTIAL OR SPECIAL DAMAGES ARISING IN CONNECTION WITH THE DEFAULT

TECHNOLOGY TRANSFER AND MANUFACTURING AGREEMENT

OR BREACH OF ANY OBLIGATION OF THE OTHER PARTY UNDER THIS AGREEMENT, THE SCOPE OR ANY DOCUMENTS OR APPENDICES RELATED THERETO.

Section 18. Dispute Resolution.

(a) In the event any dispute shall arise between the Discovery and Laureate with respect to any of the terms and conditions of this Agreement or the Program, then senior executives of the Discovery and Laureate shall meet as promptly as practicable after notice of such dispute to resolve in good faith such dispute.

(b) If Discovery and Laureate are unable to satisfactorily resolve the dispute, then such dispute shall be finally settled by arbitration in accordance with this Section 18. The arbitration will be held in the State of New York, and except as noted below, shall be conducted in accordance with the rules of the American Arbitration Association (or such successor organization) by two (2) arbitrators appointed, one by each Party (the "Panel". If the Panel appointed cannot agree on the resolution of the dispute within sixty (60) days after the dispute is submitted to them, the Panel shall thereupon appoint a third arbitrator, and if the Panel fails to agree upon a third arbitrator within thirty (30) days after a deadlock is declared by either arbitrator, a third arbitrator will be appointed by the American Arbitration Association (or such successor organization) upon the request of either arbitrator. The Panel shall have no authority to vary from or ignore the terms of this Agreement and shall be bound by controlling law. Notwithstanding the foregoing, the Parties may seek judicial intervention for emergency relief, such as restraining orders and injunctions where appropriate.

(c) Any decision by the Panel shall be binding upon the Parties and may be entered as final judgment in any court having jurisdiction. The cost of any arbitration proceeding shall be borne by the Parties, as the Panel shall determine if the Parties have not otherwise agreed. The Panel shall render their final decision in writing to the Parties.

Section 19. Indemnification. (a) Laureate shall indemnify Discovery and its Affiliates and their respective officers, directors, consultants, contractors, employees and agents from any loss, cost, damage or expense (a "Loss") from any lawsuit, action, claim, demand, assessment or proceeding (a "Claim") for: (i) personal injury to Program participants or to any employee or other personnel of Discovery or its Affiliates occurring directly or indirectly during the conduct of the Program as a result of Laureate's gross negligence or intentional misconduct; (ii) Laureate's breach of any of the representations, warranties or covenants contained in this Agreement; (iii) Laureate's transportation, storage, use, handling or disposal of hazardous materials used in or generated by Laureate's activities under this Agreement, (iv) Laureate's use of the Process Dedicated Equipment other than in connection with the Program; and (v) any willful misconduct by any Laureate employee or other personnel with respect to Laureate's activities under this Agreement; provided, that if any if such Loss or Claim arises in whole or in part from Discovery's gross negligence or intentional misconduct, then the amount of such loss shall be reduced by an amount in proportion to the percentage of Discovery's responsibilities for such Loss as determined in pursuant to Section 18 or in a binding settlement between the Parties.

(b) Discovery shall indemnify Laureate and its Affiliates and their respective officers, directors, consultants, contractors, employees and agents (the "Laureate Group") from any Claim or Loss arising from or related to (i) personal injury or property damage to a participant in the Program, any employee of the Laureate Group or any Third Party directly or indirectly caused by the Materials, Product-Dedicated Equipment, Process Consumables, Drug Product, Drug Substance or the Program; (ii) the harmful or otherwise unsafe effect of the Materials, Process Consumables, Drug Product or Drug Substance including, without limitation, a Claim based upon Discovery's or any other person's use,

TECHNOLOGY TRANSFER AND MANUFACTURING AGREEMENT

consumption, sale, distribution or marketing of any substance, including the Materials, Process Consumables, the Drug Substance or the Drug Product; (iii) the negligence, gross negligence or intentional misconduct or inaction of Discovery in the performance of its obligations under this Agreement or Scope related to the Program; (iv) the infringement of any patents or other intellectual property rights vested in any Third Party, or (v) Discovery's breach of any of the representations, warranties or covenants contained in this Agreement; provided, that, if such Loss or Claim arises in whole or in part from Laureate's gross negligence or intentional misconduct, then the amount of such Loss that Discovery shall indemnify the Laureate Group for pursuant to this Section 19 shall be reduced by an amount in proportion to the percentage of Laureate's responsibilities for such Loss as determined pursuant to Section 18 or in a binding settlement between the Parties.

(c) Discovery agrees and acknowledges that Discovery shall:

(i) bear (i.a.) risk of loss, destabilization, alteration or contamination of the Drug Product or Materials due to any and all causes or hazards unless Laureate is found to be in material non-compliance with cGMP, the Process or Laureate SOP, grossly negligent or have engaged in intentional misconduct, and (i.b.) risk of injury to persons or property alleged to have been caused by the design, manufacture, testing, instructions or warnings accompanying the Drug Product or Materials or the use or unavailability of the Drug Product or Materials, including without limitation, patent or other intellectual property rights of Third Parties alleged to have been infringed by the manufacture, use, importation, or sale of the Drug Product or Materials, unless any such injury was caused by the material non-compliance by Laureate with cGMP, the Process or Laureate SOP, Laureate's gross negligence or Laureate's engaging in intentional misconduct.

(ii) Assume full responsibility and liability for any and all direct damages to Laureate in the event that the handling of Materials, Process Consumables, Drug Product or Drug Substance on its premises, or the installation or use of the Product-Dedicated Equipment, in accordance with Laureate SOP, the Scope and the terms of this Agreement results in contamination of equipment, facilities, personnel or Third Parties by noxious, toxic, infectious, and/or corrosive agents (collectively, "Contaminants") in the Materials, Process Consumables, Drug Product, Drug Substance or associated materials [***] and to the extent that said contamination can be conclusively determined to have arisen from such materials, wherein infectious agents refers to any microbiological or viral agents of infection, including but not limited to bacteria, fungus, mycoplasmas, prions, and viruses. For purposes of the preceding sentence, Laureate's direct damages shall be deemed to include all Third Party damages, including consequential or incidental damages, that the arbitrators in accordance with Section 18 or a court of law or other governing tribunal or agency determines Laureate to be responsible and/or liable for by virtue of its handling of Materials, Process Consumables, Drug Product or Drug Substance on its premises, or the use of the Product-Dedicated Equipment, in accordance with Laureate SOP, the Scope and the terms of this Agreement. To the extent that any contamination of equipment, facilities, personnel or Third Parties results from Laureate's negligence or failure to follow its SOP or the terms of this Agreement, then Laureate will assume full responsibility and liability for any such direct damages, provided, however, that Laureate's conduct in this regard had an effect that contributed materially to the contamination or its consequences.

Laureate agrees to use reasonable commercial efforts to mitigate any direct damages in the event of a contamination incident caused by Materials, Process Consumables, Drug Products, Drug Substance or associated materials.

Information marked by [***] has been omitted pursuant to a request for confidential treatment. The omitted portion has been separately filed with the Securities and Exchange Commission.

TECHNOLOGY TRANSFER AND MANUFACTURING AGREEMENT

(d) Upon receipt of notice of any Claim that may give rise to a right of indemnity from the other Party hereto, the Party seeking indemnification (the "Indemnified Party") shall give written notice thereof to the other Party, (the "Indemnifying Party") of such claim. Such notice shall indicate the nature of the Claim and the basis therefor. Promptly after a Claim is made for which the Indemnified Party seeks indemnity, the Indemnified Party shall permit the Indemnifying Party, at its option and expense, to assume the complete defense of such Claim; provided, that: (i) the Indemnified Party will have the right to participate in the defense of any such Claim at its own cost and expense; (ii) the Indemnified Party may assume the complete defense of such claim at the Indemnifying Party's cost and expense if the Indemnified Party shall have reasonably concluded upon the advice of outside counsel satisfactory to the Indemnifying Parties and its counsel, that there is a conflict of interest between the Indemnified Party and the Indemnifying Party; (iii) the Indemnifying Party will conduct the defense of any such Claim with due regard for the business interests and potential related liabilities of the Indemnified Party; and (iv) the Indemnifying Party shall, prior to making any settlement, consult with the Indemnified Party as to the terms of such settlement. The Indemnifying Party will not, in defense of any such Claim, except with the consent of the Indemnified Party, consent to the entry of any judgment or enter into any settlement which does not include, as an unconditional term thereof, the giving by the claimant or plaintiff to the Indemnified Party of a release from all liability in respect thereof. After notice to the Indemnified Party of the Indemnifying Party's election to assume the defense of such Claim, the Indemnifying Party shall only be liable to the Indemnified Party for such reasonable legal or other expenses subsequently incurred by the Indemnified Party in connection with the defense thereof at the request of the Indemnifying Party. As to those Claims with respect to which the Indemnifying Party does not elect to assume control of the defense, the Indemnifying Party shall be liable for all reasonable legal or other expenses incurred by the Indemnified Party in connection with the defense thereof and the Indemnified Party will afford the Indemnifying Party an opportunity to participate in such defense at the Indemnifying Party's own cost and expense, and will not settle or otherwise dispose of any of the same without the consent of the Indemnifying Party.

(e) Notwithstanding anything in this Agreement to the contrary, Laureate's liability to Discovery under this Agreement shall be limited as follows:

(i) Laureate's aggregate liability resulting from the loss, destabilization, alteration or contamination of Drug Product of a particular Batch in crude or purified form as a result of Laureate's breach of this Agreement, failure to comply with Master Batch Record or negligence, wherein such Drug Product is lost, destabilized, altered or contaminated such that it cannot be used in clinical trials or cannot be placed into commerce, shall not exceed the Service Fees received by Laureate with respect to the Batch in question; and

(ii) Laureate's aggregate liability in respect of any Claim by Discovery shall not exceed the amount of the Service Fees received by Laureate with respect to the Batch that is alleged to have caused the injury giving rise to such Claim.

Section 20. Warranties, Representations and Covenants

(a) Discovery hereby represents and warrants to Laureate that it or its Third Party suppliers, as applicable, have legal title and/or a valid license to the Materials, process patents, Drug Product and Drug Substance and that Laureate's performance of the Program will not violate or infringe on the patents, industrial property rights, trade secrets, trademarks, tradenames, servicemarks, copyrights or any other intellectual property rights of any Third Party. Discovery further represents and warrants that it is, and shall at all times throughout the term of this Agreement remain, entitled to supply Materials, Drug Product, Drug Substance and Discovery Confidential Information to Laureate.

TECHNOLOGY TRANSFER AND MANUFACTURING AGREEMENT

(b) Discovery shall notify Laureate immediately if Discovery knows or should know that it is no longer entitled to supply the Materials, product and process patents, Drug Products, Drug Substance, any other materials and/or Discovery Confidential Information to Laureate or that the use by Laureate of such materials and/or information infringes or is alleged to infringe any rights (including any intellectual or industrial property rights) vested in any Third Party.

(c) Discovery hereby represents and warrants to Laureate that Discovery has performed all required testing to assure that the Materials, Drug Substance and Drug Product are safe, stable and effective and are and will be in compliance with all federal, state and local laws and regulations required for use and distribution and testing of such materials in connection with the clinical trials and the commercialization of the Drug Product, and that such materials pose no safety or environmental risk and that such Materials meet the Specifications.

(d) Discovery hereby represents to Laureate that any technical or regulatory information or documentation supplied by Discovery or on its behalf to Laureate (including, but not limited to, process details, analytical methods, Specifications, development reports, technology transfer documents, plans, engineering documents and other documents) and required for execution of the Program is accurate and suitable for its intended use.

(e) Each Party hereby represents and warrants to the other Party that it has full power and authority to enter into, deliver and perform its obligations under this Agreement, and it has taken all action required to authorize the execution and delivery of this Agreement and to consummate the transactions contemplated hereby, and the person signing this Agreement on behalf of such Party has been duly authorized to act on behalf of and to bind such Party.

(f) Laureate warrants and represents that (i) the Program will be performed diligently, (ii) it will use all commercially reasonable efforts to achieve the estimated deadlines for the Program, and (iii) the Drug Product will meet in all material respects the Specifications set forth in the Program at the time of delivery to Discovery. Laureate makes no warranties that the Program will result in any specific quantity of Drug Product.

(g) THE EXPRESS WARRANTIES OF LAUREATE SET FORTH IN SECTION 20 ARE IN LIEU OF ALL CONDITIONS, WARRANTIES AND STATEMENTS IN RESPECT OF THE PROGRAM AND/OR THE DRUG PRODUCT, WHETHER EXPRESS OR IMPLIED BY STATUTE, CUSTOM OF THE TRADE OR OTHERWISE, INCLUDING ANY SUCH CONDITION, WARRANTY OR STATEMENT RELATING TO THE DESCRIPTION OR QUALITY OF THE DRUG PRODUCT UPON COMPLETION OF LAUREATE'S SERVICES, ITS FITNESS FOR A PARTICULAR PURPOSE OR USE UNDER ANY CONDITIONS, WHETHER OR NOT KNOWN TO LAUREATE, AND THAT ANY SUCH CONDITION, WARRANTY OR STATEMENT IS EXCLUDED FROM THIS AGREEMENT.

Section 21. Force Majeure. Either Party shall be excused from performing its respective obligations under this Agreement if its performance is delayed or prevented by any event beyond such Party's reasonable control, including, but not limited to, acts of God, fire, explosion, weather, government proclaimed states of emergency, disease, war, terrorism, insurrection, civil strife, riots, union strikes, labor stoppages, government action, or power failure (each, a "Disability") provided that such performance shall be excused only to the extent of and during such Disability; provided, further, that Laureate shall use commercially reasonable efforts to remedy any disability within its reasonable control. Any time specified for completion of performance in the Scope falling due during or subsequent to the occurrence of any Disability shall be automatically extended for a period of time

TECHNOLOGY TRANSFER AND MANUFACTURING AGREEMENT

reasonably necessary to recover from such Disability. Laureate will promptly notify Discovery if, by reason of any of the events referred to herein, Laureate is unable to meet any such time for performance specified in the Scope. If any part of the Program is invalid or Materials, Process Consumables, Drug Product, Drug Substance or Other Active Ingredients are rendered unusable as a result of such Disability, Laureate will, upon written request from Discovery, but at Discovery's sole cost and expense, repeat that part of the Program affected by the Disability.

Section 22. Use of Names and Logos.

(a) Each Party shall be permitted to use the name of the other Party in the promotion of its business; provided, that such usage shall be permitted solely for: (i) product labeling and promotional purposes, (ii) sales and marketing materials; (iii) web sites; and (iv) other customary business uses agreed to by the Parties. Without the consent of the other Party, such usage shall be limited to general factual statements concerning the relationship between Laureate and Discovery, including, without limitation, that Laureate and Discovery have entered into this Agreement but shall not include any financial terms, Discovery Confidential Information or Laureate Confidential Information.

(b) Except for internal purposes, the Parties shall not be permitted to use the logo of the other Party for any purposes whatsoever without such Party's prior written consent, to be granted at the sole discretion of such Party.

Section 23. Term; Termination; Cancellation.

(a) This Agreement shall commence on the Effective Date and shall continue in full force and effect for a period of [***] years, unless (i) extended upon mutual agreement of the Parties; or (ii) terminated earlier in accordance with the other provisions of this Agreement;

(b) Except as set forth in Section 6, Discovery may for any reason and at any time terminate the Program prior to completion of the Program by giving 180 days written notice to Laureate. In such event Laureate shall comply with such notice to terminate work on the Program by the expiration of such 180 day notice period and use its commercially reasonable efforts to reduce cost to Discovery and, provided, however, that upon such termination, Discovery shall pay Laureate all of Laureate's costs incurred up to and through the expiration of such ninety (90) notice period (for each Service Fee for which the final installment payment is not due and owing prior to the expiration of such 180 day period, Laureate shall be compensated for the services performed with respect to such Service Fee on an hourly basis based on Laureate's then current hourly rates).

(c) Laureate may for any reason terminate the program by giving one year written notice to Discovery, unless Discovery consents to such shorter termination period (which consent shall not be unreasonably withheld by Discovery after giving effect to the following factors: the existence of fully-operational, alternative manufacturing facilities; regulatory review requirement; Discovery's then existing contractual obligations with respect to manufacturing facilities; and the degree of inventory buildup that may have been or is to be provided by Laureate prior to such termination).

Information marked by [***] has been omitted pursuant to a request for confidential treatment. The omitted portion has been separately filed with the Securities and Exchange Commission.

TECHNOLOGY TRANSFER AND MANUFACTURING AGREEMENT

(d) The termination of this Agreement for any reason shall not relieve either Party of its obligation to the other Party for obligations in respect of (i) compensation for services performed (Sections 8, 9 and 9 and Appendix 6); (ii) confidentiality of information (Section 10); (iii) work product (Section 11), (iv) inventions and patents (Section 12); (v) insurance (Section 14); (vi) indemnification (Section 19); and (vii) consents for advertising purposes and publications (Section 22).

Section 24. Assignment. This Agreement may not be assigned, relocated or otherwise transferred by either Party without the prior written consent of the other Party; provided, however, either Party may, without such consent, assign this Agreement (i) in connection with the transfer or sale of all or substantially all of the assets of such Party or, in the case of Discovery, the Drug Product; (ii) in the event of the merger or consolidation of a Party hereto with another company; or (iii) to any Affiliate of the assigning Party so long as the assignor remains responsible for the performance of its Affiliate hereunder; provided, however, that (i.a.) in the case of any such assignment by Laureate, such assignment may not be to any direct competitor of Discovery or involve the relocation of the Program greater than thirty (30) miles from where it is then being conducted without Discovery's consent which may not be unreasonably withheld or delayed; and (i.b.) in the case of any such assignment by Discovery, the assignee shall be reasonably credit worthy. Any purported assignment in violation of the preceding sentence shall be void. Any permitted assignee shall be required to assume in writing all obligations of its assignor under this Agreement.

Section 25. Notice. (a) All notices to be given as required in the Agreement shall be in writing and may be delivered personally, or mailed either by a reputable overnight carrier with required receipt signature or certified mail, postage prepaid, to the Parties at the addresses set forth above or at such other address as either Party may provide by written notice to the other Party in accordance with the provisions of this Section 25. Such notice shall be effective: (i) on the date sent, if delivered personally or by facsimile (receipt of which is confirmed); (ii) the date after delivery if sent by overnight carrier; or (iii) on the date received if sent by certified mail.

If to Discovery

Discovery Laboratories, Inc.
350 S. Main St., Suite 307
Doylestown, PA 18901
Attn: Legal Department
Telefax: (215) 340-3940

With a copy to:

Dickstein Shapiro Morin & Oshinsky LLP
1177 Avenue of the Americas, 41st Floor
New York, NY 10036-2714
Attn: Ira L. Kotel
Telefax: (212) 997-9880

TECHNOLOGY TRANSFER AND MANUFACTURING AGREEMENT

If to Laureate:

Laureate Pharma L.P.
201 College Road East
Princeton, NJ 08540
Attn: Robert J. Broeze, Ph.D., President
Telefax: (609) 520-3963

With a copy to:

Lowenstein Sandler PC
65 Livingston Avenue
Roseland, NJ 07068-1791
Attn: John D. Hogoboom
Telefax: (973) 597-2400

Section 26. Choice of Law. This Agreement, and all matters arising directly or indirectly hereunder, shall be governed by, and construed in accordance with the laws of the State of New York.

Section 27. Headings. The heading of each Section of this Agreement is for descriptive purposes only and shall not be deemed to modify or qualify any of the provisions, rights, or obligations set forth in this Agreement.

Section 28. Waiver/Severability. No waiver of any provision of this Agreement, whether by conduct or otherwise, in any one or more instances shall be deemed to be or be construed as a further or continuing waiver of any such provision, or of any other provision or condition of this Agreement. The invalidity of any portion of this Agreement shall not affect the validity, force or effect of the remaining portions of this Agreement. If it is ever held that any provision hereunder is too broad to permit enforcement of such provision to its fullest extent, such provision shall be enforced to the maximum extent permitted by law.

Section 29. Entire Agreement; Modification/Counterparts. This document (and the Scope and Appendices attached hereto) sets forth the entire Agreement between the Parties hereto with respect to the performance of the Program by Laureate for Discovery and as such, supersedes all prior and contemporaneous negotiations, agreements, representations, understandings, and commitments with respect thereto and shall take precedence over all terms, conditions and provisions on any Purchase Order form or form of order acknowledgment or other document purporting to address the same subject matter. This Agreement shall not be waived, released, discharged, changed or modified in any manner except by an instrument signed by the duly authorized officers of each of the Parties hereto, which instrument shall make specific reference to this Agreement and shall express the plan or intention to modify same. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument. In the event of any conflict between this Agreement and the Quality Agreement, as it may be modified as provided herein, the terms of this Agreement shall control. For purposes of execution, facsimile signatures shall be deemed originals.

This Agreement becomes effective and binding on both Parties as of the Effective Date. Should terms contained herein be at variance with the terms and conditions specified in Discovery's prior written acceptances, then the terms and conditions contained herein take precedence.

TECHNOLOGY TRANSFER AND MANUFACTURING AGREEMENT

LAUREATE PHARMA, L.P.

By: Laureate Pharma, Inc., its general partner

By: Robert J. Broeze
Name: Robert J. Broeze, Ph.D.
Title: President

DISCOVERY LABORATORIES, INC.

By: Robert J. Capetola

Name: Robert J. Capetola, Ph.D.
Title: President and Chief Executive Officer

TECHNOLOGY TRANSFER AND MANUFACTURING AGREEMENT

APPENDIX 1

Materials and Information to be Provided by Discovery

Discovery shall provide the following information and materials to Laureate:

1. A Technology Transfer Information Package that includes:
 - a. Information and procedures pertaining to the manufacture, impurities, testing, stability and use of the Drug Product, including Laureate's Product Information Questionnaires for "Contract Purification Services" and "Aseptic Filling Services" for Drug Product.
 - b. A complete copy of a representative executed Batch Record for Drug Product previously manufactured by Akorn including without limitation, all Process information, Specifications for Drug Product and all Materials, test methods and results.
 - c. A copy of the sections of the Chemistry and Manufacturing Controls section of the Investigational New Drug Application related to the above as submitted by Discovery or its Affiliates to FDA.
 - d. A Material Safety Data Sheet (MSDS) for Drug Product, Drug Substance, Other Active Ingredients and excipients.
2. Reference standards.
3. Proposed specifications for the Drug Product and intermediates and results of testing carried out by Discovery by its agents. Final specifications to be agreed upon by Laureate and communicated by Discovery
4. Product-Dedicated Equipment and Process Equipment to be provided by Discovery or Laureate and paid for by Discovery.

Product-Dedicated Equipment and Process Equipment

[***]

Information marked by [***] has been omitted pursuant to a request for confidential treatment. The omitted portion has been separately filed with the Securities and Exchange Commission.

TECHNOLOGY TRANSFER AND MANUFACTURING AGREEMENT

APPENDIX 2

Scope of Work

Outline of Activities To Be Performed By Laureate

- o Develop the Quality Agreement to be agreed upon by Laureate and Discovery defining the responsibilities of each company with respect the manufacture, testing and release of Drug Product.
- o Other than that which is supplied by Discovery, acquire equipment and other supplies necessary to make Drug Product.
- o Clean, install, calibrate and validate (in accordance with Discovery's written instructions) Discovery's existing Product-Dedicated Equipment (relocated from Discovery's Third Party manufacturer) in Laureate's manufacturing facility in Totowa for manufacture of Initial Phase Batches. Thereafter, Laureate will assess the feasibility of manufacturing batches of clinical and potential commercial supplies of Drug Product that will consistently meet Specifications.
- o At a time to be determined, remove existing Product-Dedicated Equipment and install, calibrate and validate new Product-Dedicated Equipment for manufacture of development phase, clinical trial and / or commercial batches. Thereafter, Laureate will assess the feasibility of manufacturing batches of clinical and potential commercial supplies of Drug Product that will consistently meet Specifications.
- o Perform media fills using the same vial configuration(s) as will be used in the aseptic filling of the Drug Product.
- o Create the cGMP documentation required for manufacturing and filling of Drug Product.
- o Purchase and receive production materials and supplies, if applicable; perform QC inspection and QA release for production. Receipt and inspection of materials and supplies will take place at Laureate's Princeton Facility, and materials and supplies will be transported to Laureate's Totowa Facility for manufacturing.
- o Manufacture Drug Product in accordance with cGMP requirements, as detailed in the Project Scope and Discovery's written instructions. Aseptically fill and inspect each Lot into vials at the specified product concentration in accordance with cGMP requirements. All filled vials will be transported to Laureate's Princeton Facility and inspected by Laureate's manufacturing personnel.
- o Perform Quality Control in-process testing, as required to support product manufacturing and as requested by Discovery.
- o Perform Quality Control/Quality Assurance review and manage documentation throughout the manufacturing process.
- o Provide Discovery with copies of all Batch Records used in the manufacturing process. Note: Laureate will archive the original documents on file in its Quality Assurance department.

TECHNOLOGY TRANSFER AND MANUFACTURING AGREEMENT

The Parties acknowledge and agree that the Scope shall be subject to amendment, revision and other modification throughout the term and in accordance with the Agreement

TECHNOLOGY TRANSFER AND MANUFACTURING AGREEMENT

Appendix 2-Page 2

APPENDIX 3

Testing to be Provided by Laureate

Raw materials

Review of information or Certificate of Analysis provided by Discovery or its testing vendor

Process Consumables

Identity testing as appropriate

Bulk Surfaxin product

In-process as defined by the batch record and/or protocols, where appropriate.

Filled Vials: As defined by the final product specification

TECHNOLOGY TRANSFER AND MANUFACTURING AGREEMENT

APPENDIX 4

Approved Subcontractors and Services

[***]

Appendix 4-Page 1

Information marked by [***] has been omitted pursuant to a request for confidential treatment. The omitted portion has been separately filed with the Securities and Exchange Commission.

TECHNOLOGY TRANSFER AND MANUFACTURING AGREEMENT

Appendix 4-Page 1

APPENDIX 5

Access and Audits

1. Access to the Facilities :

During production runs Discovery employees will be granted reasonable access to the manufacturing floor, if space allows. Laureate escort will be assigned and will accompany the at all times while in controlled areas of the plant. During this time it is critical that such persons:

Follow Laureate's procedures for access to its Facilities and service areas.

Follow all GMP / access / gowning / safety procedures as directed by Laureate personnel.

Do not touch or operate any equipment in the production area.

Do not direct manufacturing personnel. Suggestions or recommendations may be made to an area Manager or Director.

Do not remove any documentation or in-process data. Requests for documentation must be made in writing to an area Manager or Director. Any documentation provided in this fashion will be tracked by the area Director.

Make all requests for additional immediate in-process sampling, in writing to the area Manager or Director with full justification, prior to sampling.

Do not enter areas where production is ongoing for another Laureate client.

Do not take any photos inside any Laureate facility; provided, however, that Laureate shall reasonably provide digital photos to Discovery of Discovery's Program-related equipment, upon Discovery's written request.

Lack of adherence to these very basic guidelines will result in immediate loss of access to production areas.

2. Audits - Discovery:

Laureate will, at no cost to Discovery, support one (1) audit during each twelve (12) month period of the Program, unless a for-cause inspection by the FDA necessitates that Discovery confirm that the appropriate remedial action has been taken. If a quality issue is identified, Discovery will have the right to conduct a follow-up audit. All such follow-up audits shall be to be billed by Laureate on a time and materials basis or as specified in the Appendix 6. Thereafter any additional audits, FDA inspections or follow-up audits will be at the sole expense of Discovery.

The audit may be performed by Discovery or by an external Third Party, with Third Party costs being at the sole expense of Discovery. A maximum of three (3) auditors /

Discovery participants will be allowed to take part in the actual audit, due to space limitations and dedicated Laureate personnel availability.

Dates for the annual audit must be arranged and agreed with Laureate a minimum of one month prior to the audit. Dates for other audits will be scheduled as promptly as commercially practicable following Discovery's written request for such audit. Laureate reserves the right to make final approval of audit dates, based on availability of the facility and appropriate Laureate personnel.

Confidentiality agreements must be in place with all parties participating in the audit, prior to scheduling the audit.

Three (3) weeks before the annual audit occurs, a list of areas / topics to be covered in the audit will need to be received by Laureate. This will allow Laureate to ensure appropriate Laureate personnel availability during the audit, while also ensuring minimal impact to programs in production for other customers.

No access will be allowed into areas where production is underway for another customer.

Any audit observations being sent to Laureate for review or response must be provided by the Discovery, not directly from a Third Party auditor. Laureate will formally respond to audit findings within forty-five (45) days.

All audit observations are confidential, covered in the confidentiality agreement between Laureate and the Discovery, and may not be shared with any other party without express written permission. All Third Party auditors must also sign confidentiality agreements with Laureate confirming adherence to this condition and may not share their findings beyond the Discovery who contracts the audit, without express written permission from Laureate.

APPENDIX 6

Payment Schedule

The Service Fees shall be payable as follows:

[***]

Note: All prices subject to change based on the provisions of Section 8(a).

Information marked by [***] has been omitted pursuant to a request for confidential treatment. The omitted portion has been separately filed with the Securities and Exchange Commission.

TECHNOLOGY TRANSFER AND MANUFACTURING AGREEMENT

Appendix 6-Page 1

APPENDIX 7

Shipping

The shipment and timely arrival of samples, Drug Product, Drug Substance and other materials that Laureate produces and stores for Discovery is critical to keep the Program on schedule.

Laureate requires a minimum of one week notice prior to shipping (not prior to receipt at a remote location). One week notice is reasonable for the vast majority of the shipments. Laureate recognizes that there will be instances that will necessitate shipping materials where a one-week notice is not possible. Laureate will continue to meet those requirements, however, there will be an additional charge for shipments that need to occur with less than the one week notice. The charges for the shipping are summarized in the table below. Discovery will be responsible for the cost of shipping and insurance. Discovery will provide contact and account information for approved shipping agent. Discovery will review and authorize shipping configuration.

Prior to shipment Drug Product will be stored at Laureate under cGMP conditions that will include but not be limited to the following:

Temperature controlled (2 to 8 (Degree)C) and monitored

Controlled access

Back-up power supply

Call out service for alarms generated outside of normal business hours

Shipping Policy:

Notice Period Prior To Shipping	Shipping Charge	Additional Fee For Expedited Shipments
7 calendar days or longer	[***]	[***]
4 days to 6 days	[***]	[***]
2 days to 3 days	[***]	[***]
Same day shipping	[***]	[***]

Information marked by [***] has been omitted pursuant to a request for confidential treatment. The omitted portion has been separately filed with the Securities and Exchange Commission.

TECHNOLOGY TRANSFER AND MANUFACTURING AGREEMENT