

18-04055-6

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Office of
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April 20, 2018

Dear SEC FOIA Office:

I am requesting a copy of

Exhibit 10.9 to Form S-1 filed by Voyager Pharmaceutical Corp on 09/09/2005.

I am willing to pay up to \$61.00.

Thank you,

Diane Martin

AUS Consultants Inc.

155 Gaither Dr, Suite A

Mt. Laurel

NJ 08054

856.234.9200



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

Office of FOIA Services

May 18, 2018

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

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-04055-E

Dear Ms. Martin:

This letter is in response to your request, dated and received in this office on April 20, 2018, for access to Exhibit 10.9 to Form S-1 filed by Voyager Pharmaceutical Corp on September 9, 2005.

In connection with a previous request, access was granted to the subject exhibit. Therefore, we have determined to release the same exhibit (copy enclosed) to you. No fees have been assessed in this instance.

If you have any questions, please contact me at reidk@sec.gov or (202) 551-3504. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Lizzette Katilius as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or Archives.gov or via e-mail at ogis@nara.gov.

Sincerely,

Kay Reid

Kay Reid
FOIA Lead Research Specialist

Enclosures

FEASIBILITY, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This Feasibility, Development and Commercialization Agreement (this "Agreement") is made as of July 22, 2002, by and between Voyager Pharmaceutical Corporation, a Delaware corporation with its principal place of business at 8540 Colonnade Center Drive, Raleigh, NC 27615 ("Voyager"), and Southern Biosystems, Inc., an Alabama corporation with its principal place of business at 756 Tom Martin Drive, Birmingham, Alabama 35211 ("SBS").

RECITALS

WHEREAS, Voyager is the owner of United States Patent No. 6,242,421, covering the treatment and prevention of Alzheimer's disease;

WHEREAS, SBS is in the business of developing, commercializing and manufacturing biodegradable polymers, biomedical devices and controlled-release products for biomedical and nonbiomedical applications including products based on the DURIN(TM) System;

WHEREAS, Voyager desires to develop and commercialize a pharmaceutical product that implements Voyager's patented Alzheimer's Disease treatment methodology;

WHEREAS, Voyager desires to obtain certain rights to use SBS's proprietary drug delivery technology in connection with the development and commercialization of such a pharmaceutical product, and SBS desires to grant Voyager such rights, all on the terms and conditions set forth herein; and

WHEREAS, Voyager desires that SBS assist it in the development and commercialization of such a pharmaceutical product by performing certain feasibility, development, regulatory and manufacturing activities relating to such a product, and SBS desires to perform such activities, all on the terms and conditions set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the recitals and the mutual covenants and promises contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, do hereby agree as follows:

ARTICLE I. DEFINITIONS

Section 1.1 "Active Agent" shall mean leuprolide acetate.

Section 1.2 "Affiliate" of a Person shall mean any other Person that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such first Person. "Control" and, with correlative meanings, the terms "controlled by" and "under common control with" shall mean ownership of shares of stock having at least

50% of the voting power entitled to vote for the election of directors in the case of a corporation and at least 50% of the interest in profits in the case of a business entity other than a corporation.

Section 1.3 "Agreement" shall have the meaning set forth in the preamble hereto.

Section 1.4 "Applicable Law" shall mean the applicable laws, rules, regulations, including any rules, regulations, guidelines, or other requirements of the Regulatory Authorities, that may be in effect from time to time in the Territory.

Section 1.5 "Chair" shall have the meaning set forth in Section 6.1.

Section 1.6 "Clinical Milestone Target Date" shall have the meaning set forth in Section 4.2(a).

Section 1.7 "Clinical Trial Plan" shall have the meaning set forth in Section 4.2(a).

Section 1.8 "Clinical Trials" shall mean Phase I, Phase II, Phase III and such other tests and studies in human subjects or patients that are required by the Regulatory Authorities from time to time in connection with the Product pursuant to Applicable Law or otherwise.

Section 1.9 "CMC Data" shall mean any and all information contained in, as well as data supporting, the Chemistry, Manufacturing and Control section of an IND or NDA for the Product, and any similar information or data required with respect to any other Regulatory Approval.

Section 1.10 "Commercially Reasonable Efforts" shall mean, with respect to the research, development, Manufacture or commercialization of the Product, efforts and resources commonly used in the research-based pharmaceutical industry for a product of similar commercial potential at a similar stage in its lifecycle, taking into consideration its safety and efficacy, its cost to develop, the competitiveness of alternative products, its proprietary position, the likelihood of regulatory approval, its profitability, and all other relevant factors. Commercially Reasonable Efforts shall be determined on a market-by-market basis in the Territory. Commercially Reasonable Efforts with respect to Voyager's diligence in conducting Clinical Trials and pursuing Marketing Authorization with respect to the Product in the United States will be evaluated in view of, among other factors, Voyager's timely achievement of Clinical Milestone Target Dates (as changed from time to time in accordance with Section 4.2(a)) and Voyager and SBS's timely satisfaction of their respective obligations hereunder.

Section 1.11 "Confidential Information" shall mean (a) any and all information or material that, at any time before or after the date hereof, has been or is provided or communicated to the Receiving Party by or on behalf of the Disclosing Party pursuant to this Agreement or in connection with the transactions contemplated hereby or any discussions or negotiations with respect thereto; any data, ideas, concepts or techniques contained therein; and any modifications thereof or derivations therefrom and (b) the existence and terms of this Agreement. Confidential Information may be disclosed either orally, visually, in writing, by delivery of materials containing Confidential Information or in any other form now known or hereafter invented.

Section 1.12 "Deposit" shall have the meaning set forth in Section 7.1.

Section 1.13 "Development Activities" shall have the meaning set forth in Section 3.2.

Section 1.14 "Development Costs" shall have the meaning set forth in Section 7.1.

Section 1.15 "Development Evaluation Materials" shall have the meaning set forth in Section 3.6.

Section 1.16 "Development Formulations" shall mean the various Product prototypes developed by SBS in connection with performing the Development Activities and provided to Voyager for evaluation in accordance with the Development Plan.

Section 1.17 "Development Plan" shall have the meaning set forth in Section 3.2.

Section 1.18 "Disclosing Party" shall mean the party disclosing Confidential Information.

Section 1.19 "Effective Date" shall mean the date first above written.

Section 1.20 "Exploit" shall mean to make, have made, import, use, sell, offer for sale or otherwise dispose of a product or process, including the research, development, registration, modification, enhancement, improvement, Manufacture, storage, formulation, optimization, export, transport, distribution, promotion or marketing of a product or process.

Section 1.21 "FDA" shall mean the United States Food and Drug Administration and any successor agency thereto.

Section 1.22 "Feasibility Activities" shall mean all tests, studies and other activities that are performed in connection with the Feasibility Program, including the preparation of the Final Report.

Section 1.23 "Feasibility Evaluation Materials" shall have the meaning set forth in Section 2.3.

Section 1.24 "Feasibility Plan" shall mean the detailed program set forth in Exhibit 1.24 for developing a formulation of the Product that meets the Product Specifications and evaluating the feasibility of such formulation, as the same shall be amended from time to time in accordance with Section 6.1.

Section 1.25 "Feasibility Program" shall have the meaning set forth in Section 2.1.

Section 1.26 "FFDCA" shall have the meaning set forth in Section 5.4.

Section 1.27 "Final Report" shall mean the detailed analysis and evaluation of the Feasibility Program which shall (a) describe the methodology employed and the results achieved by SBS in conducting the Feasibility Program, (b) provide recommendations for additional

development of the Product, and (c) be in such form and include such other information as set forth in the Feasibility Plan.

Section 1.28 "Firm Order" shall have the meaning set forth in Section 5.2.

Section 1.29 "First Commercial Sale" shall mean the first sale for use or consumption by the general public of the Product in a country in the Territory after Regulatory Approval for the marketing and sale of the Product has been obtained in such country.

Section 1.30 "GAAP" shall mean United States generally accepted accounting principles consistently applied.

Section 1.31 "GLP" shall mean the current good laboratory practices applicable from time to time pursuant to Applicable Law.

Section 1.32 "GMP" shall mean the current good manufacturing practices applicable from time to time to the Manufacturing of the Product or any intermediate thereof pursuant to Applicable Law.

Section 1.33 "IND" shall mean an investigational new drug application filed with the FDA for authorization to commence human clinical trials, and its equivalent in other countries or regulatory jurisdictions in the Territory.

Section 1.34 "Indemnification Claim Notice" shall have the meaning set forth in Section 12.3.

Section 1.35 "Indemnified Party" shall have the meaning set forth in Section 12.3.

Section 1.36 "Indemnifying Party" shall have the meaning set forth in Section 12.3.

Section 1.37 "Invention" shall mean any discovery, improvement, process, formula, data, invention, know-how, trade secret, procedure, device, marketing study or other intellectual property, whether or not patentable, including any enhancement in the manufacture, formulation, ingredients, preparation, presentation, means of delivery, dosage or packaging of a product or any discovery or development of a new indication for a product.

Section 1.38 "Joint Development Team" shall have the meaning set forth in Section 6.1.

Section 1.39 "Joint Inventions" shall have the meaning set forth in Section 8.1.

Section 1.40 "Losses" shall have the meaning set forth in Section 12.1.

Section 1.41 "Major Market" shall mean each of Canada, France, Germany, Italy, Japan, the United Kingdom and the United States.

Section 1.42 "Manufacture" and "Manufacturing" shall mean, with respect to the Product, the manufacturing, processing, formulating, packaging, labeling, holding and quality control testing of such Product.

Section 1.43 "Manufacturing Cost" shall have the meaning set forth in Section 5.3.

Section 1.44 "Manufacturing Process" shall mean any process or step thereof that is necessary or useful for Manufacturing the Product or any intermediate thereof.

Section 1.45 "Marketing Authorization" shall mean an approved New Drug Application as defined in the FDCA and the regulations promulgated thereunder, or any corresponding foreign application, registration or certification, necessary or reasonably useful to market the Product in countries or regulatory jurisdictions in the Territory other than the United States, including applicable pricing and reimbursement approvals.

Section 1.46 "Minimum Royalty" shall have the meaning set forth in Section 7.3.

Section 1.47 "Net Sales" shall mean, with respect to any Person for any period, the gross amount invoiced by such Person and its Affiliates and sublicensees for the sale of the Product to unrelated third Persons in bona fide arms' length transactions, less deductions, in their normal and customary amounts for: (a) normal and customary trade, quantity and cash discounts and sales returns and allowances, including (i) those granted on account of price adjustments, billing errors, rejected goods, damaged goods, returns and rebates, (ii) administrative and other fees and reimbursements and similar payments to wholesalers and other distributors, buying groups, pharmacy benefit management organizations, health care insurance carriers and other institutions, (iii) allowances, rebates and fees paid to distributors and (iv) chargebacks; (b) freight, postage, shipping and insurance expenses to the extent that such items are included in the gross amount invoiced; (c) customs and excise duties and other duties related to the sales to the extent that such items are included in the gross amount invoiced; (d) rebates and similar payments made with respect to sales paid for by any governmental or regulatory authority such as, by way of illustration and not in limitation of the parties' rights hereunder, federal or state Medicaid, Medicare or similar state programs or any equivalent programs of a country other than the United States; (e) sales and other taxes and duties directly related to the sale or delivery of the Product (but not including taxes assessed against the income derived from such sale); (f) distribution expenses to the extent that such items are included in the gross amount invoiced; and (g) any such invoiced amounts that are not collected by such Person or its Affiliates or sublicensees. Any of the deductions listed above that involves a payment by such Person or its Affiliates or its sublicensees shall be taken as a deduction in the calendar quarter in which the payment is accrued by such entity. Deductions pursuant to subsection (g) above shall be taken in the calendar quarter in which such sales are no longer recorded as a receivable. For purposes of determining Net Sales, (x) the Product shall be deemed to be sold when invoiced and a "sale" shall not include transfers or dispositions for charitable, promotional, pre-clinical, clinical, regulatory or governmental purposes, (y) sales between or among such Person, its Affiliates and sublicensees shall be excluded from the computation of Net Sales and (z) Net Sales shall include the portion of the price charged for separate products sold along with or for use in connection with the Product which is in excess of the fair market value of such products if they were not

sold along with or in connection with the Product as reasonably determined by such Person. Net Sales shall include any amounts received by such Person, its Affiliates or sublicensees in connection with the transfer of Product to an unrelated third Person to the extent any such amounts are prepayments of, or can be offset or credited against, Product sales to such unrelated third Person. If the Product is transferred or delivered by or for such Person to a third Person but no invoice is delivered, Net Sales shall be determined based on the average gross selling price invoiced by such Person for the Product during the three (3) month period immediately preceding such transfer or delivery.

Section 1.48 "Person" shall mean an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

Section 1.49 "Phase I" shall mean all tests and studies in subjects that are required by the Regulatory Authorities from time to time pursuant to Applicable Law or otherwise to obtain sufficient data of safety, metabolism and pharmacokinetic properties and clinical pharmacology to permit initiation of Phase II for the Product, including the trials referred to in 21 C.F.R. ss. 312.21(a), as amended.

Section 1.50 "Phase II" shall mean all tests and studies in subjects that are required by the Regulatory Authorities from time to time pursuant to Applicable Law or otherwise, in addition to Phase I, to obtain sufficient data as to efficacy and dosing to permit initiation of Phase III for the Product, including the trials referred to in 21 C.F.R. ss. 312.21(b), as amended.

Section 1.51 "Phase III" shall mean all tests and studies using an extensive patient base (other than Phase I and Phase II) that are intended to provide substantial evidence of efficacy and safety in support of Marketing Authorization for the Product, including all tests and studies that are required by the FDA from time to time, pursuant to Applicable Law or otherwise, as Phase III tests and studies for the Product.

Section 1.52 "Product" shall mean a biodegradable polymeric implant (single, solid, preformed macroscopic device) for the treatment of Alzheimer's Disease in humans that utilizes the SBS Technology or the SBS Improvements and contains the Active Agent.

Section 1.53 "Product Specifications" shall mean the written specifications and quality control testing procedures for the Product determined by Voyager and amended, modified or supplemented from time to time in accordance with Section 5.8.

Section 1.54 "Project Information and Inventions" shall have the meaning set forth in Section 8.1.

Section 1.55 "Receiving Party" shall mean the party receiving Confidential Information.

Section 1.56 "Recipients" shall have the meaning set forth in Section 10.1.

Section 1.57 "Regulatory Approval" shall mean any and all approvals (including pricing and reimbursement approvals), licenses, registrations or authorizations of any Regulatory Authority, necessary for the Exploitation of the Product in a country in the Territory, including any (a) approval of the Product, including any IND, Marketing Authorization and supplements and amendments thereto; (b) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto); (c) labeling approval; and (d) technical, medical and scientific licenses.

Section 1.58 "Regulatory Authority" shall mean any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities regulating or otherwise exercising authority with respect to the Exploitation of the Product in the Territory.

Section 1.59 "SBS" shall have the meaning set forth in the preamble hereto.

Section 1.60 "SBS Improvements" shall mean any and all Inventions created, developed or acquired as a result of or in connection with the Agreement, including the Feasibility Activities, the Development Activities or SBS's Manufacturing of the Product hereunder that relate (i) solely to the SBS Technology including implant and accessory devices used in connection therewith or (ii) the application of the SBS Technology to or the combination of the SBS Technology with agents, features or processes.

Section 1.61 "SBS Indemnified Parties" shall have the meaning set forth in Section 12.2.

Section 1.62 "SBS Technology" shall mean any and all proprietary technical information, formulations, processes, know-how, data, specifications, methods of manufacture or use, characterization methods, characterization results, and other proprietary information to the extent not generally known, whether or not patentable, owned by SBS relating to its proprietary bioerodable polymeric implant technology (DURIN(TM) Biodegradable Implants) for imparting controlled release or other performance-enhancing qualities to products, including any patents (issued, pending, or subsequently filed and including all divisionals, continuations, continuations-in-part or other related United States and foreign applications).

Section 1.63 "Terminated Country" shall have the meaning set forth in Section 4.2.

Section 1.64 "Territory" shall mean all countries of the entire world except any Terminated Countries.

Section 1.65 "Test Formulations" shall mean the various Product prototypes developed by SBS in connection with performing the Feasibility Activities and provided to Voyager for evaluation in accordance with the Feasibility Plan.

Section 1.66 "Testing Laboratory" shall have the meaning set forth in Section 5.6.

Section 1.67 "Third Party Claim" shall have the meaning set forth in Section 12.3.

Section 1.68 "Unique Dose Product" shall mean a controlled release pharmaceutical product that delivers the Active Agent and with respect to which the ratio of the quantity of Active Agent delivered to the period of time in which such quantity is delivered is substantially similar to such ratio for the Product (e.g., if the Product delivers two (2) mgs of Active Agent over a one (1) month period, a product that delivers four (4) mgs of Active Agent over a two (2) month period would be a Unique Dose Product).

Section 1.69 "Voyager" shall have the meaning set forth in the preamble hereto.

Section 1.70 "Voyager Patents" shall mean any and all patents, patent applications, and other intellectual property owned or controlled by Voyager related to the treatment and prevention of Alzheimer's disease, including United States Patent No. 6,242,421.

Section 1.71 "Voyager Development Recommendations" shall have the meaning set forth in Section 3.6.

Section 1.72 "Voyager Feasibility Recommendations" shall have the meaning set forth in Section 2.3.

Section 1.73 "Voyager Indemnified Parties" shall have the meaning set forth in Section 12.1.

ARTICLE II. FEASIBILITY PROGRAM

Section 2.1 Conduct of Feasibility Program. SBS shall conduct and complete all tests, studies and other activities set forth in, or required in order to obtain the information set forth in, the Feasibility Plan (the "Feasibility Program"); provided that SBS may, at its sole discretion, elect to have selected Feasibility Activities be performed by its Affiliates and further may subcontract standard tasks and services to third Person providers of such services; provided that SBS shall be responsible for ensuring that the performance of all Feasibility Activities by its Affiliates or third Persons complies with the terms of this Agreement and in no event shall any such delegation or subcontract release SBS from any of its obligations under this Agreement. SBS shall use Commercially Reasonable Efforts to complete the Feasibility Program in accordance with the timeline set forth in the Feasibility Plan. SBS represents, warrants and covenants that it shall perform the Feasibility Program in good scientific manner and in compliance in all material respects with all Applicable Laws and good, professional clinical and laboratory practices (but not under GLP), and shall endeavor to achieve the objectives of the Feasibility Program efficiently and expeditiously. Moreover, SBS shall proceed diligently with the Feasibility Program by allocating sufficient time, effort, equipment, and skilled personnel to complete the Feasibility Program successfully and promptly. Notwithstanding the foregoing, the parties acknowledge and agree that there can be no assurances that the objectives of the Feasibility Program can be achieved, or that they can be achieved in the time set forth in the Feasibility Plan.

Section 2.2 Costs and Expenses.

(a) Subject to Section 7.1 and except as provided in Section 2.2(b), SBS shall be solely responsible for all costs and expenses incurred in connection with the performance of the Feasibility Activities, including costs and expenses of personnel, laboratory facilities and equipment, chemicals (other than the Active Agent) and other supplies.

(b) SBS shall obtain, from a vendor approved by Voyager and at Voyager's expense, all Active Agent necessary to complete the Feasibility Activities. SBS estimates that approximately 250g of Active Agent will be required for the completion of the Feasibility Activities.

Section 2.3 Test Formulations. SBS shall from time to time provide Voyager with (a) sufficient quantities of the various Test Formulations of the Product as the same are developed during the performance of the Feasibility Program and (b) such technical and other information regarding such Test Formulations as Voyager may reasonably require, in each case to enable Voyager to evaluate the scientific and commercial viability of such Test Formulations (collectively, the "Feasibility Evaluation Materials"). Voyager may evaluate the Test Formulations received from SBS and provide recommendations to the Joint Development Team for changes to the Feasibility Program (the "Voyager Feasibility Recommendations"), including the development of the Product. Any Test Formulations provided by SBS will be used by Voyager for research purposes only and shall not be used in humans.

Section 2.4 Reporting Requirements.

(a) At approximately the midpoint of the completion of the Feasibility Program, SBS shall provide Voyager with a written progress report which shall describe the Feasibility Activities that SBS has performed to date and evaluate the work performed in relation to the goals of the Feasibility Plan

(b) Within forty-five (45) days after completion of the Feasibility Program, SBS shall provide Voyager with the Final Report. Within thirty (30) days of Voyager's receipt of the Final Report, the parties shall meet, at such time and place as the parties may agree, to review the Final Report, including the results of the Feasibility Program contained therein.

(c) In addition to the written reports specified in clauses (a) and (b) above, SBS shall provide such other information as may be reasonably requested by Voyager relating to the Feasibility Program from time to time.

Section 2.5 Rights and Remedies. If SBS defaults in the performance of any of its material obligations under this Article II, which default has not been cured by SBS within sixty (60) days after receiving written notice thereof from Voyager, then Voyager may, in its sole discretion, terminate (a) the rights and obligations of the parties under Article II, Article III, Article V or Article VI on an Article-by-Article basis, or under all such Articles (in which event the license granted pursuant to Section 8.2(a) shall also terminate) or (b) the rights and obligations of the parties under Section 4.2(c) (in which event the license granted pursuant to Section 8.2(c) shall also terminate), in each case by providing immediate written notice to SBS, in which event Voyager shall have the right to perform or have performed by a third Person all

feasibility, development, regulatory or Manufacturing activities related to the Product previously allocated to SBS under the terminated provisions. The rights and remedies provided in this Section 2.5 shall be cumulative and in addition to any other rights or remedies that may be available to Voyager.

Section 2.6 Genzyme Technology. The parties acknowledge and agree that Voyager is currently in discussions with Genzyme Corporation regarding the use or acquisition of certain data and technology that may be relevant to the Product and that may accelerate, or eliminate the necessity for, the performance of certain Feasibility Activities and Development Activities. In the event that Voyager acquires the right to use such data and technology, the parties shall negotiate in good faith amendments to the terms of this Agreement that provide for the acceleration or elimination of such Feasibility Activities and Development Activities; provided that in no event shall the method for calculating Development Costs or manufacturing Costs, the royalties payable by Voyager pursuant to Section 7.3, or, except as expressly set forth in the succeeding proviso, the milestone payments payable by Voyager pursuant to Section 7.2 be amended or changed as a result of the use of such data and technology; provided further, however, that in the event that the use of such data and technology obviates the need for performance of Phase I trials for the Product, Voyager shall pay the \$250,000 milestone otherwise payable pursuant to Section 7.2(a) within thirty (30) days after receipt by Voyager of written notification from FDA that Phase I trials for the Product are not required.

ARTICLE III. DEVELOPMENT ACTIVITIES

Section 3.1 Election to Proceed. Voyager shall notify SBS in writing, within ninety (90) days after SBS's submission to Voyager of the Final Report, whether Voyager elects to proceed with further development of the Product. If Voyager notifies SBS that it does not wish to proceed with further development, or if Voyager does not deliver notice within such ninety (90) day period, then this Agreement shall be deemed to have been terminated pursuant to Section 11.2(a) as of the time of delivery of such notice or the end of such ninety (90) day period, as the case may be.

Section 3.2 Development Plan.

(a) Upon the election by Voyager to proceed with development of the Product pursuant to Section 3.1, the parties shall consult to develop as soon as reasonably practicable a written plan (the "Development Plan") that sets forth (i) further development activities with respect to the Product that are necessary or desirable to enable Voyager to commence Clinical Trials for the Product (including Manufacturing Process development as required and the production by SBS of Product formulations for preclinical, toxicology and other studies) (the "Development Activities"), (ii) the party responsible for performing each Development Activity, and (iii) an estimated timeline for completion of critical development milestones in accordance with Section 3.3(b). In the event of any dispute between the parties with respect to the contents of the Development Plan, such dispute will be submitted to the Joint Development Team and resolved by the Joint Development Team in accordance with Section 6.1. The Development Plan may be amended from time to time by the Joint Development Team in accordance with Section 6.1.

(b) Prior to commencing any Development Activities, SBS shall provide Voyager with a good faith, non-binding estimate of the total amount of Development Costs required to complete the Development Activities.

Section 3.3 Conduct of Development Activities.

(a) Each of SBS and Voyager shall provide funding, conduct and complete all tests, studies and other activities set forth in, or required in order to obtain the information set forth in, the Development Plan for which it is assigned responsibility; provided that SBS may, at its sole discretion, elect to have selected Development Activities allocated to it under the Development Plan be performed by its Affiliates and further may subcontract standard tasks and services to third Person providers of such services; provided that SBS shall be responsible for ensuring that the performance of all Development Activities by its Affiliates or third Persons complies with the terms of this Agreement and in no event shall any such delegation or subcontract release SBS from any of its obligations under this Agreement. Each of SBS and Voyager represents, warrants and covenants that it shall perform the Development Activities for which it is assigned responsibility in good scientific manner and in compliance in all material respects with all requirements of Applicable Laws and good clinical and laboratory practices and under such regulatory standards (for example GLP or GMP) as shall be specified in the Development Plan, and shall endeavor to achieve the objectives of the Development Plan efficiently and expeditiously. Moreover, each of SBS and Voyager shall proceed diligently with the Development Plan by allocating sufficient time, effort, equipment, and skilled personnel to complete the Development Activities for which it is assigned responsibility successfully and promptly.

(b) The Development Plan will include good faith estimates for critical development milestones, such as completion of a GLP toxicity study, package development, trocar development, manufacturing of an initial batch of clinical materials under GMP, and preparation of documentation for submission an IND (toxicity, CMC, and initial stability).

Section 3.4 Costs and Expenses.

(a) Subject to Section 7.1 and except as provided in Section 3.4(b), SBS shall be solely responsible for all costs and expenses incurred in connection with the performance of the Development Activities for which it is assigned responsibility, including costs and expenses of personnel, laboratory facilities and equipment, chemicals (other than the Active Agent) and other supplies.

(b) SBS shall obtain, from a vendor approved by Voyager and at Voyager's expense all Active Agent necessary to complete the Development Activities for which SBS is assigned responsibility.

Section 3.5 Reporting Requirements.

(a) Within thirty (30) days after the end of each calendar quarter in which Development Activities are performed, SBS shall provide to Voyager a written progress report, which shall describe the Development Activities it has performed during such calendar quarter,

evaluate the work performed in relation to the goals of the Development Plan, and provide such other information as may be reasonably requested by Voyager with respect to the Development Activities.

(b) In addition to the written reports specified in subsection (a) above, SBS shall provide such other information as may be reasonably requested by Voyager relating to the Development Activities from time to time.

Section 3.6 Development Formulations. SBS shall from time to time provide Voyager with (a) sufficient quantities of the various Development Formulations as the same are developed during the performance of the Development Activities and (b) such technical and other information regarding such Development Formulations as Voyager may reasonably require, in each case to enable Voyager to evaluate the scientific and commercial viability of such Development Formulations (collectively, the "Development Evaluation Materials"). Voyager may evaluate the Development Formulations received from SBS and provide recommendations to the Joint Development Team for changes to the Development Plan (the "Voyager Development Recommendations").

Section 3.7 Regulatory Records. SBS shall maintain records of all Feasibility Activities and Development Activities conducted by it in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall be substantially complete and materially accurate and shall reflect all work done and results achieved in the performance of the Feasibility Activities and Development Activities, and which shall be retained by SBS for at least five (5) years after the termination of this Agreement, or for such longer period as may be required by Applicable Law. Voyager shall have the right, during normal business hours and upon reasonable notice, to inspect and copy any such records.

Section 3.8 Rights and Remedies. If SBS defaults in the performance of any of its material obligations under this Article III, which default has not been cured by SBS within sixty (60) days after receiving written notice thereof from Voyager, then Voyager may, in its sole discretion, terminate (a) the rights and obligations of the parties under Article III, Article V or Article VI on an Article-by-Article basis or under all such Articles (in which event the license granted pursuant to Section 8.2 (a) shall also terminate) or (b) Section 4.2(c) (in which event the license granted pursuant to Section 8.2(c) shall also terminate), in each case by providing immediate written notice to SBS, in which event Voyager shall have the right to perform or have performed by a third Person all development, regulatory and Manufacturing activities related to the Product previously allocated to SBS under the terminated provisions. The rights and remedies provided in this Section 3.8 shall be cumulative and in addition to any other rights or remedies that may be available to Voyager.

ARTICLE IV. REGULATORY APPROVALS

Section 4.1 Regulatory Approvals. Within ninety (90) days following the completion of the Development Activities, Voyager shall notify SBS in writing in the event that Voyager elects to commence Clinical Trials with respect to the Product. If Voyager notifies SBS that it does not wish to proceed with Clinical Trials, or if Voyager does not deliver notice within such

ninety (90) day period, then this Agreement shall be deemed to have been terminated pursuant to Section 11.2(a) as of the time of delivery of such notice or the end of such ninety (90) day period, as the case may be. Voyager shall have the sole right to develop the appropriate strategy for obtaining and maintaining Regulatory Approvals in the Territory. All INDs, Marketing Authorizations and other filings, applications or requests pursuant to or in connection with the Regulatory Approvals shall be made in the name of, and shall be owned solely by, Voyager or its designee. Voyager shall have the sole right to conduct all communications with the Regulatory Authorities with regard to the Product.

Section 4.2 Voyager Diligence.

(a) If Voyager elects to proceed with Clinical Trials for the Product, Voyager shall use Commercially Reasonable Efforts to conduct all required Clinical Trials and obtain the Regulatory Approvals necessary to Exploit the Product in the United States as soon as reasonably practicable. Voyager shall use Commercially Reasonable Efforts to commercialize the Product in the United States during the term of this Agreement commencing as soon as reasonably practicable after receipt of required Regulatory Approvals. At the same time as Voyager provides SBS with written notice of its intent to conduct Clinical Trials pursuant to Section 4.1, Voyager shall provide SBS with a written outline of its Clinical Trial strategy and timeline to support Regulatory Approval in the United States (the "Clinical Trial Plan"). The Clinical Trial Plan will include Voyager's good faith estimate as to the target dates for (i) IND filing, (ii) start of Phase III and (iii) NDA filing to support Regulatory Approval in the United States (each, a "Clinical Milestone Target Date"). Voyager shall review the Clinical Trial Plan at least on a quarterly basis and may in its reasonable discretion change such plan and any Clinical Milestone Target Date therein at any time. Voyager promptly shall notify SBS in writing in the event of any material change to the Clinical Trial Plan or in the event that any Clinical Milestone Target Date is delayed by one calendar quarter or more. At SBS's request, Voyager shall provide SBS the reasons for such change. If Voyager defaults in the performance of any of its material obligations under this Section 4.2(a), which default has not been cured by Voyager within sixty (60) days after receiving written notice thereof from SBS, then SBS may, in its sole discretion, terminate this Agreement by providing immediate written notice to Voyager.

(b) If Voyager has not applied for Regulatory Approval in (i) each other Major Market within three (3) years after obtaining Regulatory Approval for the Product in the United States or (ii) in each country in the Territory other than a Major Market within five (5) years after obtaining Regulatory Approval for the Product in the United States, or has not made the First Commercial Sale in any country within twelve (12) months after receipt of Regulatory Approval in such country, then SBS may, upon ninety (90) days prior written notice to Voyager (unless Voyager applies for such Regulatory Approval or makes such First Commercial Sale within such ninety (90) day period), terminate the rights granted to Voyager under Section 8.2 with respect to such country (each, a "Terminated Country").

(c) SBS may elect, at its sole discretion, to Exploit the Product in any Terminated Country by providing ninety (90) days prior written notice to Voyager.

(d) The remedies set forth in this Section 4.2 shall be exclusive and in lieu of any other remedies that may be available to SBS pursuant to any statutory or common law or equity with respect to any Losses of any kind or nature suffered by SBS directly or indirectly resulting from or arising out of any failure by Voyager to perform its obligations under this Section 4.2 .

Section 4.3 Cooperation of SBS. SBS shall cooperate with any and all reasonable requests for assistance from Voyager with respect to the development and commercialization of the Product and obtaining and maintaining Regulatory Approvals for the Product, including by:

(a) making its employees, consultants and other scientific staff available upon reasonable notice during normal business hours at their respective places of employment to consult with Voyager on issues arising during such development and commercialization;

(b) making its employees, consultants and other scientific staff available upon reasonable notice during normal business hours to attend meetings with Regulatory Authorities concerning the Product;

(c) disclosing and making available to Voyager, in whatever form Voyager may reasonably request, all biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, clinical, safety, Manufacturing and quality control data and other information related to the Product, the Manufacturing Process and the SBS Technology owned or controlled by SBS as is necessary or desirable to prepare, file, obtain and maintain any Regulatory Approval; and

(d) SBS shall prepare and provide to Voyager all CMC Data with respect to the Product necessary to obtain and maintain Regulatory Approvals and in a form suitable for filing by Voyager with Regulatory Authorities.

Section 4.4 Review of Filings. Voyager shall provide SBS with the opportunity for a timely review and comment on all regulatory filings proposed to be made with respect to the Product prior to their submission to a Regulatory Authority and will promptly provide SBS with copies of all communications to or from any Regulatory Authority with respect to the Product. SBS shall perform such review promptly after such filings are provided by Voyager.

Section 4.5 Rights and Remedies. If SBS defaults in the performance of any of its material obligations under this Article IV, which default has not been cured by SBS within sixty (60) days after receiving written notice thereof from Voyager, then Voyager may, in its sole discretion, terminate (a) the rights and obligations of the parties under Section 4.3, 4.4 or Article V on a case-by-case basis or under all such provisions (in which event the license granted pursuant to Section 8.2(a) shall also terminate) or (b) the rights and obligations of the parties under Section 4.2(c) (in which event the license granted pursuant to Section 8.2(c) shall also terminate), in each case by providing immediate written notice to SBS, in which event Voyager shall have the right to perform or have performed by a third Person all regulatory and Manufacturing activities related to the Product previously allocated to SBS under the terminated

provisions. The rights and remedies provided in this Section 4.5 shall be cumulative and in addition to any other rights or remedies that may be available to Voyager.

ARTICLE V. MANUFACTURING

Section 5.1 Supply Obligations. SBS shall supply Voyager with, and Voyager shall purchase from SBS, (a) all of Voyager's clinical requirements of the Product and placebos necessary in connection with Clinical Trials and (b) all of Voyager's commercial requirements of the Product; provided that SBS shall not be required to supply a number of units of Product in any calendar quarter that exceeds the reasonable maximum quarterly manufacturing capacity of SBS's manufacturing facility in Birmingham, Alabama on the date of this Agreement unless SBS otherwise agrees. These supply and purchase obligations shall continue until the earlier to occur of (i) the effective date of SBS's election to discontinue supply of Voyager's commercial requirements of Product, which effective date shall be specified in a written notice delivered by SBS to Voyager not less than 12 months prior to such effective date; provided that in no event may SBS elect to terminate its supply obligations prior to the second anniversary of the First Commercial Sale of the Product in the Territory, (ii) the termination of this Agreement and (iii) the termination of these supply and purchase obligations with respect to the Product in accordance with Sections 2.5, 3.8, 4.5 and 5.6. SBS may, in its sole discretion, subcontract with a qualified contract manufacturer in order to fulfill SBS's supply obligations to Voyager hereunder; provided that in no event shall any such subcontract release SBS from any of its obligations under this Agreement, including its obligation to deliver Product that complies with the warranty set forth in Section 5.4.

Section 5.2 Forecasting, Order and Delivery of Products.

(a) Forecasting. Within ninety (90) days of Voyager's election to commence Clinical Trials with respect to the Product, Voyager shall submit an estimate of the quantities of the Product (and placebos, if any) that Voyager expects to purchase from SBS during the succeeding eight (8) calendar quarters. Thereafter, on or before the thirtieth (30th) day of each following calendar quarter, Voyager shall submit an updated forecast of its requirements of the Product from SBS for the succeeding eight (8) calendar quarters. These forecasts shall be non-binding and shall be used by SBS for planning purposes only.

(b) Firm Orders. Not later than ninety (90) days prior to commencement of each calendar quarter, Voyager shall submit to SBS a purchase order for such quantities of the Product (and placebos, if any) as Voyager commits to purchase from SBS during such calendar quarter, with a statement of the dates on which delivery shall be required and shipping instructions therefore (a "Firm Order"). SBS shall confirm to Voyager in writing, within five (5) days after receipt thereof, the receipt by SBS of each Firm Order submitted in accordance with this Section 5.2, and shall be obligated to deliver the specified quantity of the Product (and placebos) in accordance with the delivery schedule set forth in such Firm Order. SBS shall exercise its best efforts to comply with changes to a Firm Order that Voyager may request after receipt by SBS of such Firm order but shall not be liable for its inability to do so. Firm Orders may be amended by mutual agreement of the parties. In the event that the terms of any Firm Order are not consistent with this Agreement, the terms of this Agreement shall prevail.

(c) **Delivery and Risk of Loss.** SBS shall deliver the quantities of the Product (and placebos) set forth in each Firm order on the delivery date specified therein, to a location designated in writing by Voyager, FOB (as defined in the UCC) SBS's facility in Birmingham, Alabama. Title to the Products shall pass to Voyager at the time of delivery.

(d) **Invoice and Payment.** SBS shall promptly invoice Voyager for all quantities of the Product delivered in accordance herewith. Invoices shall be accompanied by a certificate of analysis and a certificate of compliance with the warranty set forth in Section 5.4 for each invoiced batch of the Product, in such form as is reasonably acceptable to Voyager. Subject to Section 5.6, payment with respect to a shipment shall be due thirty (30) days after receipt by Voyager of such shipment of the Product and the invoice and certificates with respect thereto; provided, however, that if Voyager rejects such shipment pursuant to Section 5.6, then payment shall be due within sixty (60) days after receipt by Voyager of notice from the Testing Laboratory that the invoiced Product is conforming or, subject to Section 5.6, receipt by Voyager of replacement Product, as the case may be. In the event of any inconsistency between an invoice and this Agreement, the terms of this Agreement shall control. All payments shall be made in accordance with Section 7.4.

Section 5.3 Price. The parties hereby agree that the price (the "Manufacturing Cost") for Voyager's requirements of:

(a) clinical supplies of the Product (and placebos) shall be equal to SBS's fully allocated cost to Manufacture the Product (and placebos) in accordance with all Applicable Laws calculated in accordance with Exhibit 5.3.

(b) commercial supplies of the Product shall be equal to (A) SBS's fully allocated cost to Manufacture the Product in accordance with all Applicable Laws calculated in accordance with Exhibit 5.3, multiplied by (B) 1.25.

SBS shall notify Voyager in advance of any material increase in Manufacturing Cost.

Section 5.4 Warranty. SBS warrants that, at the time of delivery of the Product to Voyager: (a) such Product will have been Manufactured, held and shipped in accordance with the Regulatory Approvals for the Product, applicable GMP and all other Applicable Law; (b) such Product will have been Manufactured in accordance, and be in conformity, with the Product Specifications and will conform with the certificate of analysis provided pursuant to Section 5.2; (c) such Product will not be adulterated or misbranded under the Federal Food, Drug, and Cosmetic Act, as amended (the "FFDCA"), and similar provisions of the laws of other countries as to which Regulatory Approvals have been granted with respect to the Product; (d) title to such Product will pass to Voyager as provided herein free and clear of any security interest, lien or other encumbrance; (e) such Product will have been Manufactured in facilities that are in material compliance all Applicable Laws at the time of such Manufacture (including applicable inspection requirements of FDA and other Regulatory Authorities); and (f) such Product may be introduced into interstate commerce pursuant to the FFDCA.

Section 5.5 Non-Conforming Product. SBS shall not deliver to Voyager any Product that fails to conform in any respect to the warranty set forth in Section 5.4. In the event that any Product shall fail to pass the quality control testing conducted by SBS, (i) SBS shall notify Voyager thereof within one (1) business day, (ii) SBS shall not release the batch from which such Product was taken, and (iii) the parties shall agree upon appropriate corrective steps to be taken. Voyager, at its option, may investigate the cause of such failure, or require SBS to do so, in which case SBS shall provide Voyager with a written report summarizing the results of the SBS's investigation, all at the expense of SBS.

Section 5.6 Failure or Inability to Supply Product.

(a) **Notification of Inability to Supply.** In the event that SBS, at any time during the term of this Agreement, shall have reason to believe that it will be unable to supply Voyager with the full quantity of the Product forecasted to be ordered or actually ordered by Voyager in a timely manner and in conformity with the warranty set forth in Section 5.4 (whether by reason of force majeure or otherwise), SBS shall promptly notify Voyager thereof. Promptly thereafter, the parties shall meet to discuss how Voyager shall obtain such full quantity of conforming Product. Compliance by SBS with this Section 5.6 shall not relieve SBS of any other obligation or liability under this Agreement, including any obligation or liability under clause (b) or (c) below.

(b) **Failure to Supply Conforming Product.** In the event that Voyager reasonably determines, within thirty (30) days after delivery thereof by SBS, that any Product supplied by SBS does not conform to the warranty set forth in Section 5.4, Voyager shall give SBS notice thereof (including a sample of such Product). SBS shall undertake appropriate testing of such sample and shall notify Voyager whether it has confirmed such non-conformity within thirty (30) days after receipt of such notice from Voyager. If SBS notifies Voyager that it has not confirmed such non-conformity, the parties shall submit the disputed batch to an independent testing laboratory mutually acceptable to the parties (the "Testing Laboratory") for testing. The findings of the Testing Laboratory shall be binding on the parties, absent manifest error. The expenses of the Testing Laboratory shall be borne by SBS if the testing confirms the non-conformity and otherwise by Voyager. If the Testing Laboratory or SBS confirms that a batch of Product does not conform to the warranty set forth in Section 5.4, SBS shall promptly (i) supply Voyager with a conforming quantity of the Product at SBS's expense or (ii) reimburse Voyager for all reasonable costs Voyager may have directly incurred with respect to such non-conforming Product, including any Manufacturing Cost paid by Voyager with respect to such Product, which costs Voyager shall have the right to offset against any payments owed by Voyager to SBS under this Agreement. The rights and remedies provided in this clause shall be cumulative and in addition to any other rights or remedies that may be available to Voyager.

(c) **Rights and Remedies.**

(i) If SBS fails two (2) or more times within any twelve (12) consecutive month period to supply the full quantity of Product specified in a Firm Order by the delivery date specified therein and in conformity with the warranty set forth in Section 5.4, Voyager may, in its sole discretion, terminate (A) the rights and obligations of the parties under

Article V (in which event the license granted Section 8.2(a) shall also terminate) or (B) the rights and obligations of the parties under Section 4.2(c) (in which event the license granted pursuant to Section 8.2(c) shall also terminate), in each case by providing immediate written notice to SBS, and thereafter Voyager may Manufacture Product itself or purchase its requirements for Product from a third Person. The rights and remedies provided in this Section 5.6 shall be cumulative and in addition to any other rights or remedies that may be available to Voyager.

Section 5.7 Costs and Expenses. SBS shall be solely responsible for all costs and expenses incurred in connection with the Manufacture of supplies of the Product pursuant to this Article V, including costs and expenses of personnel, testing, including quality control and stability, Manufacturing facilities and equipment, the Active Agent, raw materials, excipients, labeling, packaging materials and all other supplies of any kind used in connection with Manufacturing the Product (and placebos), which costs shall be included in the calculation of Manufacturing Costs in accordance with Section 5.3; provided, however, that Voyager (i) shall reimburse to SBS, within 30 days after receipt of an invoice and reasonable supporting documentation therefor, the cost of any piece of Manufacturing equipment or other fixed asset procured by SBS after the date hereof and required to manufacture the Product hereunder; provided that the cost of such equipment or asset is \$25,000 or less, and (ii) may, if it so determines in its sole and absolute discretion, purchase (and retain title to) and make available for use by SBS any other piece of Manufacturing equipment or other fixed asset that SBS requests for use in connection with the Manufacture of the Product; provided further, that Voyager, in its sole discretion but upon reasonable advance notice to SBS, may from time to time, at its cost, supply to SBS materials (including the Active Agent) to be used in the Manufacture of the Product, in which event the cost of such materials shall not be included in calculating Manufacturing Cost for the Products for which they were used.

Section 5.8 Amendment of Product Specifications and Manufacturing Process.

(a) **Rights and Limitations.** Voyager reserves the right to amend, modify or supplement the Product Specifications or the Manufacturing Process unilaterally and in its sole discretion for the purpose of complying with the Regulatory Approvals, GMP, other Applicable Law, or, upon ninety (90) days prior notice, for any other reasonable business purpose. Voyager shall promptly supply SBS with appropriate documentation relating to any such changes to the Product Specifications or Manufacturing Process to the extent that such changes affect SBS's Manufacturing of the Product hereunder. In the event that SBS cannot reasonably implement or comply with such changes to Product Specifications (it being acknowledged and agreed by SBS that increase in Manufacturing Cost shall not constitute a valid justification for failure to implement or comply with such changes), then SBS shall not be required to implement or comply with such changes. SBS may not amend, modify or supplement the Product Specifications or the Manufacturing Process for the Product in any respect without the prior written consent of Voyager, which consent shall not be unreasonably withheld or delayed.

(b) **Amendment to Regulatory Approvals; Costs and Expenses.** In the event that Voyager amends, modifies or supplements the Product Specifications or the Manufacturing Process for the Product, or consents to any such amendment, modification or supplement by SBS, SBS shall provide to Voyager any such documentation or other information with respect

thereto as Voyager may reasonably request in order to obtain or maintain any Regulatory Approval or comply with GMP or Applicable Law. Voyager shall reimburse SBS for reasonable costs that are actually incurred by SBS in connection with any such change requested by Voyager, including reasonable costs of capital equipment and process upgrades, obsolescence of raw materials, goods-in-process, packaging materials and supplies and finished goods not suitable for use in the business or operations of SBS or any of its Affiliates; provided, however, that Voyager's liability for such reimbursement shall be limited to levels of inventory that are customary in pharmaceutical manufacturing operations. SBS shall be solely responsible for any and all costs and expenses incurred by it or Voyager and its Affiliates and sublicensees as a result of any amendment, modification or supplementation of the Product Specifications or the Manufacturing Processes by SBS not requested by Voyager, or requested by Voyager as a result of SBS's failure to Manufacture Product in conformity with the warranty set forth in Section 5.4, which costs shall not be included in the Manufacturing Costs.

Section 5.9 Testing, Assays, Stability and Quality Assurance.

(a) **Testing Requirements.** With respect to the Product or any intermediate thereof Manufactured or supplied by SBS, SBS shall be responsible for the performance of and compliance with all Product testing required by the Product Specifications, the Manufacturing Processes and Regulatory Approvals for the Product and all Applicable Law. SBS agrees to implement and maintain such processing control procedures as Voyager may reasonably request, including the assignment of identification numbers to each lot of Product and the maintenance of production records, quality control records, batch records and related information.

(b) **Retention of Samples.** SBS shall take and retain, for such period as may be required by Applicable Law or such longer period as otherwise reasonably required by Voyager, samples of Product (i) sufficient to satisfy SBS's obligations under this Agreement, GMP and Applicable Law with respect to its Manufacturing of the Product, (ii) sufficient to perform quality control testing and stability testing in accordance with this Agreement, the Regulatory Approvals for the Product, GMP and all other Applicable Law, and (iii) as otherwise reasonably required by Voyager, and in each case shall specify the control number and the date of Manufacture thereof. Further, SBS shall submit to Voyager, upon Voyager's written request, such samples, materials and quality control records as Voyager may reasonably request.

(c) **Stability Testing.** SBS shall perform stability testing of the Product in accordance with the Product Specifications, the Manufacturing Process, the Regulatory Approvals, GMP and other Applicable Law, and such other requirements and processes as Voyager shall reasonably determine from time to time. If SBS confirms a stability failure with respect to the Product, SBS shall notify Voyager thereof within twenty-four (24) hours and the parties shall discuss in good faith appropriate corrective action. SBS shall promptly implement any such corrective action.

(d) **Maintenance of Facilities.** SBS shall ensure, that any and all necessary licenses, registrations, and Regulatory Authority approvals have been obtained in connection with any facilities and equipment used in connection with the manufacture of the Product by SBS. SBS shall maintain such facilities and equipment in a state of repair and operating

efficiency consistent with the requirements of the Product Specifications, the Regulatory Approvals, the Manufacturing Processes, GMP and all other Applicable Law. Prior to each use of any equipment in Manufacturing the Product, SBS shall implement a cleaning validation protocol with respect to such equipment, including the cleaning and maintenance thereof, in accordance with any procedures reasonably established by Voyager and notified to SBS, the Product Specifications, the Regulatory Approvals and the Manufacturing Processes, GMP and all other Applicable Law. SBS shall maintain in such facilities adequate and segregated (if required) holding accommodations for the Product, the Active Agent, and the excipients, packaging components, and other items used in Manufacturing the Product in accordance with the Product Specifications, the Regulatory Approvals and the Manufacturing Process, GMP and all other Applicable Law. If required under Applicable Law, all Product shall be held by SBS in a separate segregated area until delivery to Voyager.

(e) **Quality Assurance Procedures.** Without limitation of the foregoing, SBS agrees to implement, in connection with the Manufacture of the Product, quality assurance and quality control procedures, including validation protocols, process change procedures and methods of statistical analysis for cleaning validation that are reasonably satisfactory to Voyager.

Section 5.10 Inspection by Voyager. SBS agrees that Voyager and its agents shall have the right, upon reasonable prior notice to SBS, to inspect any facility at which the Product or any intermediate thereof is manufactured as well as the Manufacturing of the Product and any intermediates thereof, as applicable, including inspection of (a) the materials used in the Manufacture of the Product, (b) the holding facilities for such materials, (c) the equipment used in the Manufacture of the Product, and (d) all records relating to such Manufacturing and each such manufacturing facility. Following such audit, Voyager shall discuss its observations and conclusions with SBS and corrective actions shall be agreed upon by Voyager and SBS within thirty (30) days thereafter. SBS shall implement such corrective action within sixty (60) days after the parties reach such agreement, unless otherwise agreed in writing by the parties.

Section 5.11 Notification of Inspections; Communications. SBS shall notify Voyager by telephone within one (1) business day, and in writing within five (5) business days, after learning thereof, of any proposed or unannounced visit or inspection of any facility at which the Product, or any intermediate thereof, is Manufactured, or of any Manufacturing Process used in connection with the Manufacture of the Product, by any Regulatory Authority, and shall permit Voyager or its agents to be present and participate in such visit or inspection. SBS shall provide to Voyager a copy of any report and other written communications received from such Regulatory Authority in connection with such visit or inspection, and any written communications received from such Regulatory Authority relating to the Product or any facility or Manufacturing Process used in connection with the Manufacture of the Product, within three (3) business days after receipt thereof, and shall consult with Voyager concerning the response of SBS to each such communication. SBS shall provide Voyager with a copy of all draft responses for comment as soon as possible and all final responses for review and approval, which shall not be unreasonably withheld or delayed, within five (5) business days prior to submission thereof.

Section 5.12 Manufacturing Records. SBS shall maintain, or cause to be maintained, (i) all records necessary to comply with GMP and all other Applicable Law relating to the

Manufacture of the Product, (ii) all Manufacturing records, standard operating procedures, equipment log books, batch records, laboratory notebooks and all raw data relating to the Manufacturing of the Product, and (iii) such other records as Voyager may reasonably require in order to ensure compliance by SBS with the terms of this Agreement. All such material shall be retained for such period as may be required by GMP and all other Applicable Law or for such longer period as Voyager may reasonably require; provided, however, that all records relating to the Manufacturing, stability and quality control of each batch of the Product shall be retained at least until the first anniversary of the end of the approved shelf life for all Product from such batch.

Section 5.13 Labeling. Voyager shall specify all labeling to be used on the Product and the packaging thereof. SBS agrees to use such labeling (and only such labeling) on the Product, and not to use such labeling on any other product. To the extent permissible under Applicable Law, at SBS's request (and expense if compliance with such request increases any costs related to the Product), Voyager shall cause the packaging of the Product to display, in a manner reasonably acceptable to SBS and Voyager, the name and logo of SBS (or an Affiliate) and to identify SBS as a developer of such Product. SBS shall grant Voyager appropriate licenses in order to fulfill its obligations under this Section 5.13.

ARTICLE VI. JOINT DEVELOPMENT TEAM

Section 6.1 Joint Development Team. Upon initiation of the Feasibility Program, the parties shall establish a joint development team (the "Joint Development Team") which shall consist of two (2) representatives appointed by each party. The chairperson of the Joint Development Team shall be a representative of Voyager (the "Chair"). Each party may, from time to time, change one or more of its representatives by written notice to the other party. The Joint Development Team shall be responsible for and establish procedures for the management of the Feasibility and Development Programs in accordance with the Feasibility and Development Plans and shall serve as points of contact between the parties to coordinate activities and ensure that the parties perform their respective obligations (if any) diligently in accordance with the Feasibility Plan and the Development Plan. The Joint Development Team shall meet at least once per month (either by telephone or in person, as agreed to by SBS and Voyager) to review the planning and the progress of the Feasibility and Development Programs and to consider recommendations regarding, and to make changes to, the Feasibility and Development Plans and performance of the Feasibility and Development Programs. In performing its functions, the Joint Development Team shall attempt to reach all decisions by consensus. However, if the members cannot reach consensus with respect to any decision within a reasonable time period (which shall not be more than thirty (30) days) after careful consideration, the matter shall be referred to the chief executive officers of Voyager and SBS for review and discussion. In the event the CEOs of Voyager and SBS cannot reach agreement within a reasonable time period (which shall not be more than thirty (30) days), then the Chair shall make the final decision, which shall be final and binding on the parties. Notwithstanding the foregoing, nothing herein, and no decision made under this Section, shall be deemed to modify or supersede the express terms or conditions of this Agreement, or any decision or decision-making authority otherwise expressly provided for in this Agreement.

ARTICLE VII. PAYMENTS

Section 7.1 Development Costs.

(a) Voyager shall pay SBS's fully allocated development cost calculated in accordance with Exhibit 7.1 (the "Development Costs") for all Feasibility Activities, Development Activities and activities under and pursuant to Article IV, in each case performed by SBS.

(b) The estimated total Development Costs necessary to complete all Feasibility Activities is set forth in the Feasibility Plan, although the actual Development Costs therefor may differ. Completion of the Feasibility Plan with less effort than estimated may result in lower charges; however, additional effort from unexpected results or changes requested by Voyager may result in higher charges. SBS will not exceed the estimated costs without prior written approval from Voyager.

(c) Voyager shall pay to SBS \$120,000 upon execution of this Agreement (the "Deposit").

(d) SBS shall submit to Voyager, not later than twenty (20) business days after the end of each month during the term of this Agreement in which Development Costs are incurred, an invoice which shall set forth the actual amount of Development Costs incurred during the prior month. Voyager, within thirty (30) days of receipt of each such invoice, (i) shall pay the amount specified in such invoice, less twenty (20) percent of such invoiced amount until such time as the Deposit has been fully credited, and (ii) thereafter shall pay the full amount of each such invoice. Charges for reimbursement of purchases of Active Agent by SBS in connection with the performance of the Feasibility Activities and the Development Activities shall be invoiced separately from time to time and shall be paid by Voyager within thirty (30) days of receipt thereof. All invoices shall be sent to Voyager at the address specified in Section 13.1 unless Voyager designates otherwise in writing to SBS.

Section 7.2 Milestone Payments. Voyager shall make the milestone payments specified below to SBS within thirty (30) days following achievement of the corresponding milestone event, except that in the case of the Approval of first NDA (or equivalent) milestone event, payment shall be paid by Voyager within sixty (60) days following achievement of such milestone event:

<u>Milestone Event</u>	<u>Milestone Payment</u>
(a) <u>Initiation of the first Phase I trial for the Product</u>	<u>\$250,000</u>
(b) <u>Initiation of the first Phase III trial for the Product</u>	<u>\$250,000</u>
(c) <u>Filing of first NDA (or equivalent) for the Product</u>	<u>\$500,000</u>
(d) <u>Approval of first NDA (or equivalent) for the Product</u>	<u>\$2,000,000</u>

Section 7.3 Voyager Royalties.

(a) Subject to the terms and conditions of this Section 7.3, Voyager shall pay to SBS the following royalties based on aggregate Net Sales of the Product by Voyager, its Affiliates and sublicensees in the Territory during each calendar year (or part thereof):

Five Percent (5%) of Net Sales for that portion of aggregate Net Sales in such calendar year that is less than or equal to \$250,000,000;

Six Percent (6%) of Net Sales for that portion of aggregate Net Sales in such calendar year that exceeds \$250,000,000 but is less than or equal to \$500,000,000; and

Seven (7%) of Net Sales for that portion of aggregate Net Sales in such calendar year that exceeds \$500,000,000.

provided that Voyager shall pay SBS at least \$250,000 in royalties annually (the "Minimum Royalty") commencing with the year in which the First Commercial Sale in any country in the Territory is made. In the event that the First Commercial Sale is made at some time other than the beginning of a calendar year, the Minimum Royalty for such first year shall be prorated.

(b) Voyager's royalty payment obligations under this Section 7.3 shall commence with the First Commercial Sale of the Product and shall terminate on the termination of this Agreement. To the extent that royalties may not be collected in a certain country in the Territory under Applicable Law for the full royalty term hereunder, then the royalty due on sales in such country shall terminate after the maximum period under which royalties may be collected under Applicable Law without effect on the royalties due hereunder with respect to sales made in other countries in the Territory.

(c) Royalties shall be payable on a quarterly basis, within sixty (60) days after the end of each calendar quarter, based upon the Net Sales during such calendar quarter (or a ratable portion of the Minimum Royalty, if greater), commencing with the calendar quarter in which the First Commercial Sale of the Product is made by Voyager. Royalties shall be calculated in accordance with GAAP and with the terms of this Section 7.3. Only one royalty payment will be due on Net Sales even though the Manufacture, sale or use of a Product may be covered by more than one SBS Technology or SBS Improvement in a country. The amount paid by Voyager as a Minimum Royalty with respect to any quarter shall be fully creditable against royalties due based on Net Sales of Product for any other quarter during the same calendar year.

(d) Each royalty payment hereunder shall be accompanied by a statement showing (a) Net Sales during the applicable calendar quarter, (b) the number of units of the Product sold by Voyager on a country-by-country basis during the applicable calendar quarter, and (c) the amount of royalties due hereunder.

(e) In the event that a court or a governmental agency of competent jurisdiction requires Voyager or a Voyager Affiliate or sublicensee to grant a compulsory license to a third Person permitting such third Person to make and sell the Product in a jurisdiction in the Territory despite Voyager having exerted all reasonable efforts to oppose the granting of such compulsory license, then all Net Sales by such compulsory sublicensee shall be excluded from the royalty calculations set forth in Section 7.3(a) and the royalty rate to be paid by Voyager on such Net Sales by such compulsory sublicensee shall be the lesser of (i) the applicable royalty rate provided in Section 7.3(a) with respect to such Net Sales, and (ii) fifty (50%) of the royalty rate under such compulsory license, during the time period when such compulsory license is in effect and being exercised.

Section 7.4 Method of Payment. All payments to SBS under this Agreement shall be made by deposit of United States Dollars in the requisite amount to such bank account as SBS may from time to time designate by notice to Voyager. With respect to sales outside the United States, payments shall be calculated based on currency exchange rates for the calendar quarter for which remittance is made for royalties. For each currency, such exchange rate shall equal the arithmetic average of the daily exchange rates (obtained as described below) during the calendar quarter; each daily exchange rate shall be obtained from The Wall Street Journal, Eastern United States Edition, or, if not so available, as otherwise agreed by the parties.

Section 7.5 SBS Royalties.

(a) If SBS elects to Exploit the Product in any Terminated Countries pursuant to Section 4.2(c), subject to the terms and conditions of this Section 7.5, SBS shall pay to Voyager the following royalties based on aggregate Net Sales of the Product by SBS, its Affiliates and licensees in all Terminated Countries during each calendar year (or part thereof):

Five Percent (5%) of Net Sales for that portion of aggregate Net Sales in such calendar year that is less than or equal to \$250,000,000;

Six Percent (6%) of Net Sales for that portion of aggregate Net Sales in such calendar year that exceeds \$250,000,000 but is less than or equal to \$500,000,000; and

Seven Percent (7%) of Net Sales for that portion of aggregate Net Sales in such calendar year that exceeds \$500,000,000.

(b) SBS's royalty payment obligations under this Section 7.5 shall commence with the first commercial sale of the Product in any Terminated Country and shall terminate on the termination of this Agreement. To the extent that royalties may not be collected in a certain Terminated Country under Applicable Law for the full royalty term hereunder, then the royalty due on sales in such country shall terminate after the maximum period under which royalties may be collected under Applicable Law without effect on the royalties due hereunder with respect to sales made in other Terminated Countries.

(c) Royalties shall be payable on a quarterly basis, within sixty (60) days after the end of each calendar quarter, based upon the Net Sales during such calendar quarter, commencing with the calendar quarter in which the first commercial sale of the Product is made by SBS, its Affiliates or sublicensees in any Terminated Country. Royalties shall be calculated in accordance with GAAP and with the terms of this Section 7.5.

(d) Each royalty payment hereunder shall be accompanied by a statement showing (a) Net Sales during the applicable calendar quarter, (b) the number of units of the Product sold by SBS, its Affiliates and sublicensees in the Terminated Countries on a country-by-country basis during the applicable calendar quarter, and (c) the amount of royalties due hereunder.

(e) All payments to Voyager under this Agreement shall be made by deposit of United States Dollars in the requisite amount to such bank account as Voyager may from time to time designate by notice to SBS. With respect to sales outside the United States, payments shall be calculated based on currency exchange rates for the calendar quarter for which remittance is made for royalties. For each currency, such exchange rate shall equal the arithmetic average of the daily exchange rates (obtained as described below) during the calendar quarter; each daily exchange rate shall be obtained from The Wall Street Journal, Eastern United States Edition, or, if not so available, as otherwise agreed by the parties.

Section 7.6 Recordkeeping and Audit.

(a) SBS shall keep, or shall cause to be kept, complete and accurate books and records of all information necessary, and in sufficient detail, to determine all Development Costs, Active Agent costs, and Manufacturing Costs payable by Voyager to SBS pursuant to this Agreement and Net Sales in the Terminated Countries (if any) and the royalties payable by SBS to Voyager pursuant to this Agreement for the previous seven (7) calendar years.

(b) Voyager shall keep, or shall cause to be kept, complete and accurate books and records of all information necessary, and in sufficient detail, to determine Net Sales in the Territory and the royalties payable by Voyager to SBS pursuant to this Agreement for the previous seven (7) calendar years.

(c) Voyager shall have the right, no more than once during any twelve (12) consecutive month period during the term of this Agreement and the twelve (12) months following the termination hereof, to have the books and records kept by SBS pursuant to Section 7.6(a) (and all related work papers and other information and documents) examined by an independent accounting firm of national standing reasonably acceptable to SBS to verify SBS's calculations of the amounts of Development Costs, Active Agent costs, and Manufacturing Costs invoiced by SBS to Voyager hereunder and the accuracy of the information contained in the reports delivered by SBS pursuant to Section 7.5(d) and SBS's calculation of the royalties payable hereunder. If Voyager shall dispute any such calculation, Voyager promptly shall notify SBS and Voyager and SBS shall use good faith efforts to resolve such dispute. If Voyager and SBS are unable to resolve such dispute within thirty (30) days after Voyager notifies SBS of such dispute, then an independent accounting firm mutually agreed to by Voyager and SBS shall

resolve such dispute and such accountant's resolution shall be final and binding on the parties. Each party shall cooperate with such accountant's investigation. If, and only if, it shall be determined pursuant to the procedures set forth in this clause (c) that (i) SBS invoiced Voyager an amount greater than 105% of the total amount actually owed by Voyager or (ii) SBS paid Voyager an amount less than 95% of the total royalty amount actually owed by SBS, then in each case SBS shall reimburse Voyager for all of its costs related to such examination and shall pay all costs and expenses of the mutually agreed accountant, if any; otherwise Voyager shall bear all of its costs related to such examination and shall pay all costs and expenses of the mutually agreed accountant, if any.

(d) SBS shall have the right, no more than once during any twelve (12) consecutive month period during the term of this Agreement and the twelve (12) months following the termination hereof, to have the books and records kept by Voyager pursuant to Section 7.6(b) (and all related work papers and other information and documents) examined by an independent accounting firm of national standing reasonably acceptable to Voyager to verify the accuracy of the information contained in the reports delivered by Voyager pursuant to Section 7.3(d) and Voyager's calculation of the royalties payable hereunder. If SBS shall dispute any such information or calculation, SBS promptly shall notify Voyager and SBS and Voyager shall use good faith efforts to resolve such dispute. If SBS and Voyager are unable to resolve such dispute within thirty (30) days after SBS notifies Voyager of such dispute, then an independent accounting firm mutually agreed to by SBS and Voyager shall resolve such dispute and such accountant's resolution shall be final and binding on the parties. Each party shall cooperate with such accountant's investigation. If, and only if, it shall be determined pursuant to the procedures set forth in this clause (d) that Voyager paid SBS an amount less than 95% of the total royalty amount actually owed by Voyager, then Voyager shall reimburse SBS for all of its costs related to such examination and shall pay all costs and expenses of the mutually agreed accountant, if any; otherwise SBS shall bear all of its costs related to such examination and shall pay all costs and expenses of the mutually agreed accountant, if any.

(e) If, as a result of the procedures set forth in clause (c) or (d) above, any amount paid by a party pursuant to the terms hereof shall be found to have been incorrectly calculated, the appropriate party promptly shall pay to the other party the amount necessary to correct such payment error.

(f) All financial books and records maintained by the parties pursuant hereto shall be maintained in accordance with GAAP.

ARTICLE VIII. INTELLECTUAL PROPERTY

Section 8.1 Ownership

(a) SBS shall own all right, title and interest in and to the SBS Technology and the SBS Improvements. Voyager shall, and shall cause its Affiliates, sublicensees and subcontractors hereunder to, promptly disclose in writing to SBS the development, making, conception or reduction to practice of any SBS Technology and the SBS Improvements and shall and does hereby, and shall cause its Affiliates, sublicensees and subcontractors to, assign to SBS

any and all right, title or interest Voyager or its Affiliates, sublicensees or subcontractors may have in or to the SBS Technology and the SBS Improvements. Voyager hereby appoints, and shall cause its Affiliates, sublicensees and subcontractors to appoint, SBS as their attorney-in-fact for the purpose of executing such documents in their respective names as may be necessary or desirable to carry out the purposes of this subsection.

(b) Voyager shall own all right, title and interest in and to (i) the Voyager Patents and (ii) any and all Inventions and other intellectual property created, developed or acquired as a result of or in connection with the Agreement including the Feasibility Activities, the Development Activities or SBS's Manufacturing of the Product hereunder, relating to clinical uses of the Active Agent (whether for treatment of Alzheimer's Disease or otherwise) (the "Project Information and Inventions"); provided, however, that the Project Information and Inventions shall not include any right, title or interest, express or implied, in or to the SBS Technology or the SBS Improvements. SBS shall, and shall cause its Affiliates, sublicensees and subcontractors to, promptly disclose in writing to Voyager the development, making, conception or reduction to practice of any Project Information and Inventions and shall and does hereby, and shall cause its Affiliates, sublicensees and subcontractors to, assign to Voyager any and all right, title or interest SBS or its Affiliates, sublicensees and subcontractors may have in or to the Project Information and Inventions. SBS hereby appoints, and shall cause its Affiliates, sublicensees and subcontractors to appoint, Voyager as their attorney-in-fact for the purpose of executing such documents in their respective names as may be necessary or desirable to carry out the purposes of this subsection.

(c) Any Inventions and other intellectual property created, developed or acquired as a result of or in connection with the Feasibility Activities, the Development Activities or SBS's Manufacturing of the Product hereunder (including any data or information generated as a result of or in connection with the Feasibility Activities and Development Activities, regardless of whether such data or information is included in any report or information delivered by SBS to Voyager hereunder), other than the Inventions owned by either SBS or Voyager exclusively as set forth in Section 8.1(a) and (b), shall be jointly owned by the parties ("Joint Inventions"). Except as otherwise set forth herein or agreed upon in writing by the parties, each party shall have all the rights and privileges of a joint owner under the patent laws of the United States with respect to the Joint Inventions, including the right to exploit and grant licenses and sublicenses to patents covering Joint Inventions, without accounting to the other party. Each party shall, and shall cause its Affiliates to, promptly disclose in writing to the other party the development, making, conception or reduction to practice of any Joint Invention. Additionally, each party agrees to cooperate with and provide reasonable assistance to the other party in filing, prosecuting and perfecting patent and other intellectual property rights covering Inventions related to the subject matter of this Agreement owned by the other party at the other party's expense.

(d) It is understood and agreed that, except as expressly provided in Section 8.2 hereof, nothing contained in this Agreement or otherwise shall be construed to mean that one party will obtain any rights, by implication or otherwise, in or to any proprietary right of the other party. In particular, SBS will not obtain any right, title or interest in or to the Voyager Patents and Project Information and Inventions and Voyager will not obtain any right, title or

interest in or to the SBS Technology and SBS Improvements, except as provided in Section 8.2 hereof.

(e) Any and all information or material related to an Invention assigned to a party pursuant to the terms of this Agreement shall constitute Confidential Information of such party which shall be deemed the Disclosing Party with respect to such Confidential Information.

Section 8.2 License Grants.

(a) Voyager hereby grants to SBS a limited, royalty-free, nonexclusive license, without right to sublicense (except to the extent, and only to the extent, necessary to permit a qualified contract manufacturer to Manufacture Product in accordance with Section 5.1), under the Voyager Patents and Project Information and Inventions solely to perform its obligations under Article II, Article III and Article V, which grant shall expire on the termination of this Agreement for any reason or otherwise in accordance with Sections 2.5, 3.8, 4.5 or 5.6.

(b) SBS hereby grants to Voyager a worldwide, royalty-bearing, exclusive (including with regard to SBS and its Affiliates) license, with right to sublicense (subject to Section 8.2(d)), under the SBS Technology and the SBS Improvements, to Manufacture, have Manufactured, import, use, sell, offer for sale and otherwise Exploit the Product in the Territory, which grant shall expire on the termination of this Agreement for any reason.

(c) In the event that SBS has the right and elects to Exploit the Product in any Terminated Country pursuant to Section 4.2(c), Voyager hereby grants to SBS in such Terminated Country a royalty bearing, exclusive license, with the right to sublicense (subject to Section 8.2(e)) under the Voyager Patents and Project Information and Inventions, and the right to use all regulatory filings, Clinical Trial data and CMC data and all other intellectual property owned by Voyager, in each case to the extent solely related to the Product, and the right to cross-reference any and all regulatory filings with respect to the Product, solely for purposes of Exploiting the Product in such Terminated Country, which grant shall expire on the termination of this Agreement for any reason or otherwise in accordance with Section 2.5, 3.8, 4.5 or 5.6.

(d) Voyager may sublicense its rights under Section 8.2(b), subject to the following conditions: (i) such sublicense shall be subject to the terms and conditions of this Agreement; and (ii) the rights of SBS under this Agreement shall not be prejudiced, reduced or limited in any way as a result of such sublicense of rights. Additionally, if Voyager sublicenses its rights to develop or commercialize the Product (other than ordinary distributor arrangements), it shall: (1) provide SBS with a copy of the proposed sublicense agreement in a time frame that reasonably permits SBS to review and comment on the sublicense agreement and a final copy of the sublicense agreement; and (2) the sublicense agreement shall be subject to the approval of SBS which shall not be unreasonably withheld or delayed.

(e) SBS may sublicense its rights under Section 8.2(c), subject to the following conditions: (i) such sublicense shall be subject to the terms and conditions of this Agreement; and (ii) the rights of Voyager under this Agreement shall not be prejudiced, reduced or limited in any way as a result of such sublicense of rights. Additionally, if SBS sublicenses its

rights to develop or commercialize the Product (other than ordinary distributor arrangements), it shall: (1) provide Voyager with a copy of the proposed sublicense agreement in a time frame that reasonably permits Voyager to review and comment on the sublicense agreement and a final copy of the sublicense agreement; and (2) the sublicense agreement shall be subject to the approval of Voyager which shall not be unreasonably withheld or delayed.

Section 8.3 Prosecution and Maintenance of Intellectual Property Rights. The responsibility for preparing, filing and prosecuting patent applications and for maintaining patents and other intellectual property rights (and for managing any interference proceedings relating to the foregoing) covering any Invention owned by a party, and all costs related thereto, shall be the responsibility of such party. The parties shall by mutual agreement prepare, file and prosecute patent applications and maintain patents and other intellectual property rights (and manage any interference proceedings relating to the foregoing) covering any Joint Invention, and all costs related thereto, shall be shared equally between the parties.

Section 8.4 Third Person Litigation.

(a) Regarding SBS Technology and Improvements. In the event that during the term of this Agreement any Person institutes against SBS or Voyager any action that alleges that the use of the SBS Technology or the SBS Improvements in connection with the Exploitation of the Product in the Territory in accordance with the terms hereof infringes the intellectual property rights held by such Person, then, as between SBS and Voyager, SBS, at its sole expense, shall have the sole obligation to contest, and assume direction and control of the defense of, such action, including the right to settle such action on terms determined by SBS; provided that in no event shall SBS enter into any settlement that adversely affects the interests of Voyager or its Affiliates, whether under this Agreement or otherwise, without Voyager's prior written consent, which shall not be unreasonably withheld or delayed. Voyager, at SBS's expense, shall use all reasonable efforts to assist and cooperate with SBS as reasonably requested by SBS in such action. If, as a result of any such action, a judgment is entered by a court of competent jurisdiction from which no appeal can be taken or from which no appeal is taken within the time permitted for appeal, or a settlement is entered into by SBS, such that any SBS Technology or the SBS Improvements cannot be used in connection with the Exploitation of the Product in the Territory without infringing the intellectual property rights of such Person, then Voyager shall have the right either to (i) terminate this Agreement immediately or (ii) take such actions as it deems necessary to protect its interests, including the right to obtain a license from such Person and to offset the cost of such license against any amounts owed to SBS hereunder; provided that the amount offset by Voyager shall not exceed 50% of the royalty rate then payable by Voyager pursuant to Section 7.3.

(b) Regarding the Voyager Patents. In the event that during the term of this Agreement any Person institutes against SBS any action that alleges that the use of the Voyager Patents in connection with the Exploitation of the Product in the Territory in accordance with the terms hereof infringes the intellectual property rights held by such Person, then, as between SBS and Voyager, Voyager, at its sole expense, shall have the sole obligation to contest, and assume direction and control of the defense of, such action, including the right to settle such action on terms determined by Voyager; provided that in no event shall Voyager enter into any settlement

that adversely affects the interests of SBS or its Affiliates, whether under this Agreement or otherwise, without SBS's prior written consent, which shall not be unreasonably withheld or delayed. SBS, at Voyager's expense, shall use all reasonable efforts to assist and cooperate with Voyager as reasonably requested by Voyager in such action. If, as a result of any such action, a judgment is entered by a court of competent jurisdiction from which no appeal can be taken or from which no appeal is taken within the time permitted for appeal, or a settlement is entered into by Voyager, such that Voyager cannot develop or commercialize the Product in a country in the Territory, then SBS shall have the right to terminate the rights granted to Voyager under Section 8.2 with respect to such country.

Section 8.5 Exclusivity.

(a) During the term of this Agreement and, in the event of termination of this Agreement by Voyager pursuant to Section 11.2(b) or (c), for a period of one (1) year after termination hereof, SBS shall not, and shall cause its Affiliates not to, (a) conduct any activity, either on its own or through its Affiliates, or with, for the benefit of, or sponsored by any Person, that has as its goal or intent discovering, identifying, Exploiting or otherwise commercializing any Unique Dose Product, or (b) grant any license or other rights to any Person to utilize any intellectual property owned or controlled by SBS or its Affiliates (including the SBS Technology, SBS Improvements or Joint Inventions) for the purpose of discovering, identifying, Exploiting or otherwise commercializing any Unique Dose Product, in each case other than as expressly provided in this Agreement.

(b) SBS acknowledges and agrees that the restrictions set forth in clause (a) above are reasonable and necessary to protect the legitimate interests of Voyager and that Voyager would not have entered into this Agreement in the absence of such restrictions, and that any violation or threatened violation of any provision of clause (a) above will result in irreparable injury to Voyager. SBS also acknowledges and agrees that in the event of a violation or threatened violation of any provision of clause (a) above, Voyager shall be entitled to preliminary and permanent injunctive relief, without the necessity of proving irreparable injury or actual damages and without the necessity of having to post a bond, as well as to an equitable accounting of all earnings, profits and other benefits arising from any such violation. The rights provided in the immediately preceding sentence shall be cumulative and in addition to any other rights or remedies that may be available to Voyager. Nothing in this Section 8.5 is intended, or should be construed, to limit Voyager's right to preliminary and permanent injunctive relief or any other remedy for a breach of any other provision of this Agreement.

(c) Voyager acknowledges and agrees that SBS may develop and commercialize, either for itself, its Affiliates, or for third parties, products, other than Unique Dose Products during the period specified in clause (a) above, which contain the Active Agent intended for uses other than for treatment of Alzheimer's Disease but which may be used or prescribed in a manner similar to the Product without authorization from SBS, and that SBS may have no control over such use or prescription.

Section 8.6 Technology Transfer. If (a) necessary to permit Voyager to exercise its rights pursuant to Sections 2.5, 3.8, 4.5, or 5.6(c), or (b) SBS is unable or unwilling to supply

Voyager with all of its commercial requirements for Product, or (c) SBS elects not to continue supply of Voyager's commercial requirements pursuant to Section 5.1(i), then in any such case SBS shall (i) promptly disclose to Voyager or its designee such SBS Technology and SBS Improvements and any know-how related thereto as is necessary or useful for Voyager or such designee to develop, Manufacture and commercialize the Product, and (ii) from time to time thereafter, as reasonably requested by Voyager, have its representatives meet with representatives of Voyager or its designee to enable Voyager or such designee to develop, Manufacture and sell the Product; provided that SBS may require any designee of Voyager to enter into a reasonable and customary confidentiality agreement with SBS that requires that Confidential Information communicated to such designee by SBS pursuant to this Section 8.6 shall be kept confidential and used only in performance of such designee's obligations to Voyager, and provided further that Voyager shall be responsible for the compliance by any designee that is not approved in advance by SBS (which approval shall not be unreasonably withheld or delayed) with the terms and conditions of such confidentiality agreement. Voyager shall reimburse SBS for any reasonable expenses incurred by SBS in connection with any transfer pursuant to clause (b) or (c) above.

ARTICLE IX. REPRESENTATIONS AND WARRANTIES

Section 9.1 Representations and Warranties of Each Party. Each party hereby represents, warrants and covenants to the other party as follows:

(a) Such party (i) is duly incorporated and in good standing under the laws of the jurisdiction of its incorporation, (ii) has full power and authority to own its property and assets and to carry on its business as it is now being conducted and as it is contemplated to be conducted by this Agreement, (iii) has the power and authority and the legal right to enter into this Agreement and perform its obligations hereunder, and (iv) has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such party and constitutes a legal, valid and binding obligation of such party and is enforceable against it in accordance with its terms subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered a proceeding at law or equity.

(b) Such party is not aware of any pending or threatened litigation (and has not received any communication) that alleges that such party's activities related to this Agreement have violated, or that by conducting the activities contemplated herein such party would violate, any of the intellectual property rights of any other Person.

(c) All necessary consents, approvals and authorizations of all regulatory and governmental authorities and other Persons required to be obtained by such party in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained.

(d) The execution and delivery of this Agreement and the performance of such party's obligations hereunder (i) do not and will not conflict with or violate any requirement of applicable law or regulation or any provision of the articles of incorporation or bylaws of such party and (ii) do not and will not conflict with, violate, or breach, or constitute a default or require any consent under, any contractual obligation or court or administrative order by which such party is bound.

Section 9.2 Additional Representations of SBS. SBS represents, warrants and covenants to Voyager as follows:

(a) SBS owns all right, title and interest in and to the SBS Technology and the SBS Technology is not subject to any lien, encumbrance or claim of ownership by any third Person.

(b) To SBS's knowledge and belief, the SBS Technology has not and does not infringe upon, misappropriate or otherwise violate the patent or intellectual property rights of any other Person.

(c) There is no claim, litigation, judgment or settlement pending or existing, or to SBS's knowledge and belief threatened, with or against SBS relating to the SBS Technology.

(d) To SBS's knowledge and belief, there is no pre-clinical or clinical data or information concerning the SBS Technology that suggests that there may exist quality, toxicity, safety or efficacy concerns that could reasonably be expected to impair the utility or safety of the Product.

(e) Neither SBS nor any of its Affiliates has been debarred or is subject to debarment and neither SBS nor any of its Affiliates will use in any capacity, in connection with the services to be performed under this Agreement, any Person who has been debarred pursuant to Section 306 of the FFDCA, or who is the subject of a conviction described in such section. SBS agrees to inform Voyager in writing immediately if it or any Person who is performing services hereunder is debarred or is the subject of a conviction described in Section 306, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of SBS's knowledge, is threatened, relating to the debarment or conviction of SBS or any Person performing services hereunder.

Section 9.3 Additional Representations of Voyager. Voyager represents, warrants and covenants to SBS as follows:

(a) Voyager owns all right, title and interest in and to the Voyager Patents and the Voyager Patents are not subject to any lien, encumbrance or claim of ownership by any third Person.

(b) To Voyager's knowledge and belief, the Voyager Patents have not and do not infringe upon, misappropriate or otherwise violate the patent or intellectual property rights of any other Person.

(c) There is no claim, litigation, judgment or settlement pending or existing, or to the best of Voyager's knowledge and belief threatened, with or against Voyager relating to the Voyager Patents.

(d) To Voyager's knowledge and belief, there is no pre-clinical or clinical data or information concerning the Active Agent that suggests that there may exist quality, toxicity, safety or efficacy concerns that could reasonably be expected to impair the utility or safety of the Product.

Section 9.4 Disclaimer of Other Warranties. EXCEPT AS SET FORTH IN THIS AGREEMENT, THE PARTIES MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF QUALITY, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT

ARTICLE X. CONFIDENTIALITY

Section 10.1 Confidential Information. Except to the extent expressly permitted by this Agreement and subject to the provisions of Sections 10.2 and 10.3, at all times during the term of this Agreement and for ten (10) years following the termination hereof, the Receiving Party (a) shall keep completely confidential and shall not publish or otherwise disclose any Confidential Information furnished to it by the Disclosing Party, except to those of the Receiving Party's employees, Affiliates, sublicensees, subcontractors or consultants who have a need to know such information (collectively, "Recipients") to perform such Party's obligations hereunder (and who shall be advised of the Receiving Party's obligations hereunder and who are bound by confidentiality obligations with respect to such Confidential Information no less onerous than those set forth in this Agreement) and (b) shall not use Confidential Information of the Disclosing Party directly or indirectly for any purpose other than performing its obligations or exercising its rights hereunder. The Receiving Party shall be jointly and severally liable for any breach by any of its Recipients of the restrictions set forth in this Agreement.

Section 10.2 Exceptions to Confidentiality. The Receiving Party's obligations set forth in this Agreement shall not extend to any Confidential Information of the Disclosing Party:

(a) that is or hereafter becomes part of the public domain by public use, publication, general knowledge or the like through no wrongful act, fault or negligence on the part of a Receiving Party or its Recipients;

(b) that is received from a third party without restriction and without breach of any agreement between such third party and the Disclosing Party;

(c) that the Receiving Party can demonstrate by competent evidence was already in its possession without any limitation on use or disclosure prior to its receipt from the Disclosing Party;

(d) that is generally made available to third parties by the Disclosing Party without restriction on disclosure; or

(e) that the Receiving Party can demonstrate by competent evidence was independently developed by the Receiving Party.

Section 10.3 Disclosure

(a) Each party may disclose Confidential Information to the extent that such disclosure is:

(i) made in response to a valid order of a court of competent jurisdiction or other governmental body of a country or any political subdivision thereof of competent jurisdiction; provided, however, that the Receiving Party shall first have given notice to the Disclosing Party and given the Disclosing Party a reasonable opportunity to quash such order and to obtain a protective order requiring that the Confidential Information and/or documents that are the subject of such order be held in confidence by such court or governmental body or, if disclosed, be used only for the purposes for which the order was issued; and provided further that if a disclosure order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such court or governmental order shall be limited to that information which is legally required to be disclosed in such response to such court or governmental order; or

(ii) otherwise required by law or regulation, in the opinion of outside legal counsel to the Receiving Party, which shall be provided to the Disclosing Party at least 24 hours prior to the Receiving Party's disclosure of the Confidential Information pursuant to this Section 10.3;

(b) Voyager may disclose Confidential Information to the extent that such disclosure is:

(i) made to the Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information;

(ii) made to third Persons as may be necessary or useful in connection with the Exploitation of the SBS Technology and SBS Improvements licensed to Voyager hereunder, including subcontracting and sublicensing transactions in connection therewith, provided that Voyager shall in each case obtain from the proposed third Person recipient a written confidentiality undertaking containing confidentiality obligations no less onerous than those set forth in this Article X; or

(iii) a disclosure of the existence and terms of this Agreement to existing or potential securityholders of Voyager; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information.

Section 10.4 Notification. The Receiving Party shall notify the Disclosing Party immediately, and cooperate with the Disclosing Party as the Disclosing Party may reasonably request, upon the Receiving Party's discovery of any loss or compromise of the Disclosing Party's Confidential Information.

Section 10.5 Remedies. Each party agrees that the unauthorized use or disclosure of any information by the Receiving Party in violation of this Agreement will cause severe and irreparable damage to the Disclosing Party. In the event of any violation of this Article X, the Receiving Party agrees that the Disclosing Party shall be authorized and entitled to obtain from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, without the necessity of proving irreparable harm or monetary damages, as well as any other relief permitted by applicable law. The Receiving Party agrees to waive any requirement that the Disclosing Party post bond as a condition for obtaining any such relief.

Section 10.6 Use of Names. Neither party shall mention or otherwise use the name, insignia, symbol, trademark, trade name or logotype of the other party (or any abbreviation or adaptation thereof) in any publication, press release, promotional material or other form of publicity without the prior written approval of such other party in each instance. The restrictions imposed by this Section 10.6 shall not prohibit either party from making any disclosure identifying the other party that is required by Applicable Law. Further, Voyager and its Affiliates and sublicensees shall have the right to use the name of SBS and its Affiliates to the extent necessary in connection with the Exploitation of the SBS Technology and SBS Improvements as contemplated by this Agreement, including subcontracting and sublicensing transactions in connection therewith.

Section 10.7 Press Releases. Except as expressly provided in Section 10.3, neither party shall make a press release or other public announcement regarding this Agreement, the terms hereof or the transactions contemplated hereby without the prior written approval of the other party. Each party shall provide the other with the proposed text of any such press release or public announcement for review and approval, which approval shall not be unreasonably withheld, as early as possible, but in no event less than five (5) business days in advance of the publication, communication or dissemination thereof; provided, however, that the receiving party shall be deemed to have approved any such press release or public announcement if it fails to notify the proposing party in writing of any objections to such press release or public announcement within four (4) business days of receipt by the receiving party of the text of such public announcement.

ARTICLE XI. TERM AND TERMINATION

Section 11.1 Term. This Agreement shall commence as of the Effective Date and shall remain in force until the terminated in accordance with this Article XI.

Section 11.2 Termination In addition to any other provision of this Agreement expressly providing for termination of this Agreement, this Agreement may be terminated as follows:

(a) Voyager may terminate this Agreement at any time for any reason by giving SBS sixty (60) days' prior written notice.

(b) Voyager may terminate this Agreement pursuant to Section 8.4 in accordance with the terms thereof.

(c) This Agreement may be terminated at any time by either party:

(i) to the extent permissible under Applicable Law, immediately upon written notice if the other party shall file in any court or agency, pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of that party or of its assets, or if the other party proposes a written agreement of composition or extension of its debts, or if the other party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof, or if the other party shall propose or be a party to any dissolution or liquidation, or if the other party shall make an assignment for the benefit of its creditors,

(ii) in the event of any default by the other party in the performance of any of its material obligations herein contained, including a party's failure to pay the other amounts when due, which default has not been cured by the defaulting party within thirty (30) days after receiving written notice thereof from the nondefaulting party, or

(iii) pursuant to Section 13.2.

Section 11.3 Effect of Termination.

(a) The termination of this Agreement shall be without prejudice to any rights or obligations of the parties that may have accrued prior to such termination, and the provisions of Sections 3.7, 5.5, 5.12, 7.6, 8.1, 8.3, 8.5, Articles I, IX, X, XII and XIII, and this Section 11.3 shall survive the termination of this Agreement. Except as otherwise expressly provided herein, termination of this Agreement in accordance with the provisions hereof shall not limit remedies that may otherwise be available in law or equity.

(b) Upon termination of this Agreement, (i) each party, at the request of the other, shall return all data, files, records and other materials in its possession or control containing or comprising the other party's Inventions or other Confidential Information except one copy of which may be retained for archival purposes and (ii) all licenses and other rights granted by each party to the other under Section 8.2 shall terminate.

(c) Upon termination of this Agreement by Voyager pursuant to Section 11.2(a), Voyager shall pay SBS in accordance with the terms hereof, to the extent such amount exceeds any uncredited amount of the Deposit at the time of such termination, for all activities performed by SBS under this Agreement through the date of termination and for all costs not refundable to SBS or otherwise useable by SBS or its Affiliates in respect of which SBS reasonably made commitments in connection with the performance of its obligations hereunder before the date of delivery of such notice of termination, and Voyager shall have no other liability or obligation to SBS in respect of such termination.

(d) SBS shall have the right to retain any portion of the Deposit uncredited at the time of termination of this Agreement unless this Agreement is terminated by Voyager pursuant to Section 11.2(b) or (c), or upon termination of the parties' rights and obligations under

Article II pursuant to Section 2.5, in which event SBS promptly shall refund to Voyager the balance of the Deposit, if any, uncredited at the time of such termination.

Section 11.4 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by SBS are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code, licenses of right to "intellectual property" as defined under Section 101 of the United States Bankruptcy Code. The parties agree that Voyager, as licensee, and SBS, as licensor, of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the United States Bankruptcy Code. The parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against SBS under the United States Bankruptcy Code, Voyager shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in Voyager's possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon Voyager's written request therefor, unless the party subject to such proceeding elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under (a) above, following the rejection of this Agreement by or on behalf of SBS upon written request therefor by Voyager. The parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against Voyager under the United States Bankruptcy Code, and an assignment of this Agreement is made for the benefit of creditors of Voyager, then the rights and obligations of Voyager under this Agreement may be transferred and assigned only to another Person engaged in the business of developing and commercializing pharmaceutical products that would reasonably be capable of performing the obligations set forth in this Agreement.

ARTICLE XII. INDEMNIFICATION

Section 12.1 SBS Indemnification. SBS shall indemnify Voyager, its Affiliates and their respective directors, officers, employees and agents (the "Voyager Indemnified Parties"), and defend and save each of them harmless, from and against any and all claims, lawsuits, losses, damages, liabilities, penalties, costs and expenses (including reasonable attorneys' fees and disbursements) (collectively, "Losses") incurred by any of them in connection with, arising from or occurring as a result of (i) the breach by SBS of any of its obligations under this Agreement, (ii) the breach or inaccuracy of any representation or warranty made by SBS in this Agreement, (iii) any Third Party Claim made by any Person relating to the use of the SBS Technology or the SBS Improvements by Voyager, its Affiliates or sublicensees, including any claim of infringement or misappropriation of the patent, trademark or other intellectual property rights of such Person; or (iv) the enforcement by Voyager of its rights under this Section 12.1, except, in each case, for those Losses for which Voyager has an obligation to indemnify SBS Indemnified Parties pursuant to Section 12.2, as to which Losses each party shall indemnify the other to the extent of their respective liability for the Losses.

Section 12.2 Voyager Indemnification. Voyager shall indemnify SBS, its Affiliates and their respective directors, officers, employees and agents (the "SBS Indemnified Parties"), and defend and save each of them harmless, from and against any and all Losses incurred by any of them in connection with, arising from or occurring as a result of (i) the breach by Voyager of any of its obligations under this Agreement, (ii) the breach or inaccuracy of any representation or

warranty made by Voyager in this Agreement, (iii) any Third Party Claim made by any Person relating to the use of the Voyager Patents by SBS, including any claim of infringement or misappropriation of the patent, trademark or other intellectual property rights of such Person, (iv) any Third Party Claim made by any Person relating to death, personal injury or property damage arising out of or resulting from the Exploitation of the Product (unless such Third Party Claim arises or results from the breach or inaccuracy of any representation or warranty made by SBS herein or any breach by SBS of any of its obligations hereunder), or (v) the enforcement by SBS of its rights under this Section 12.2, except, in each case, for those Losses for which SBS has an obligation to indemnify Voyager Indemnified Parties pursuant to Section 12.1, as to which Losses each party shall indemnify the other to the extent of their respective liability for the Losses.

Section 12.3 Indemnification Procedure.

(a) Notice of Claim. The indemnified party (the "Indemnified Party") shall give the indemnifying party (the "Indemnifying Party") prompt written notice (an "Indemnification Claim Notice") of any Losses or discovery of facts upon which such Indemnified Party intends to base a request for indemnification under Section 12.1 or 12.2, but in no event shall the Indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss are known at such time). The Indemnified Party shall furnish promptly to the Indemnifying Party copies of all papers and official documents received in respect of any Losses.

(b) Third Party Claims. The obligations of an Indemnifying Party under this Article XII with respect to Losses arising from claims of any third Person that are subject to indemnification as provided for in Section 12.1 or 12.2 (a "Third Party Claim") shall be governed by and be contingent upon the following additional terms and conditions:

(i) Control of Defense. At its option, the Indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within thirty (30) days after the Indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the Indemnifying Party shall not be construed as an acknowledgment that the Indemnifying Party is liable to indemnify any Indemnified Party in respect of the Third Party Claim, nor shall it constitute a waiver by the Indemnifying Party of any defenses it may assert against any Indemnified Party's claim for indemnification. Upon assuming the defense of a Third Party Claim, the Indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the Indemnifying Party which shall be reasonably acceptable to the Indemnified Party. In the event the Indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall immediately deliver to the Indemnifying Party all original notices and documents (including court papers) received by any Indemnified Party in connection with the Third Party Claim. Subject to clause (ii) below, if the Indemnifying Party assumes the defense of a Third Party Claim, the Indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of the Third Party Claim. In the event that it is ultimately determined that

the Indemnifying Party is not obligated to indemnify, defend or hold harmless an Indemnified Party from and against the Third Party Claim, the Indemnified Party shall reimburse the Indemnifying Party for any and all costs and expenses (including attorneys' fees and costs of suit) and any Losses incurred by the Indemnifying Party in its defense of the Third Party Claim with respect to such Indemnified Party.

(ii) Right to Participate in Defense. Without limiting Section 12.3(b)(i), any Indemnified Party shall be entitled to participate in, but not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose; provided, however, that such employment shall be at the Indemnified Party's own expense unless (A) the employment thereof has been specifically authorized by the Indemnifying Party in writing, (B) the Indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 12.3(b)(i) (in which case the Indemnified Party shall control the defense), or (C) the interests of the Indemnified Party and the Indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both parties under applicable law, ethical rules or equitable principles

(iii) Settlement. With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that will not result in the Indemnified Party's becoming subject to injunctive or other relief or otherwise adversely affect the business of the Indemnified Party in any manner, and as to which the Indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the Indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the Indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in connection with Third Party Claims, where the Indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 12.3(b)(i), the Indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss provided that it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld or delayed). The Indemnifying Party shall not be liable for any settlement or other disposition of a Loss by an Indemnified Party that is reached without the written consent of the Indemnifying Party. Regardless of whether the Indemnifying Party chooses to defend or prosecute any Third Party Claim, no Indemnified Party shall admit any liability with respect to, or settle, compromise or discharge, any Third Party Claim without the prior written consent of the Indemnifying Party (which consent shall not be unreasonably withheld or delayed).

(iv) Cooperation. Regardless of whether the Indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the Indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and

the Indemnifying Party shall reimburse the Indemnified Party for all its reasonable out-of-pocket expenses in connection therewith.

(v) Expenses. Except as provided above, the reasonable and verifiable costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any Third Party Claim shall be reimbursed on a calendar quarter basis in arrears by the Indemnifying Party, without prejudice to the Indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the Indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

Section 12.4 Insurance. Commencing not later than thirty (30) days prior to the first use in humans of the Product and thereafter for at least five (5) years after the expiration or termination of this Agreement, each party shall obtain from a licensed and reputable insurer, and maintain on an on-going basis, products liability insurance with at least Ten Million Dollars (\$10,000,000) in coverage for each occurrence. Coverage shall be on a per occurrence rather than a claims made basis. The policy shall name the other party to this Agreement and its Affiliates as an additional insured. The policy shall provide that each of the parties will be notified of the cancellation or any restrictive amendment of the policy at least thirty (30) days prior to the effective date of such cancellation or amendment. None of the parties shall violate, or permit to be violated, any conditions of such insurance policy, and each of the parties shall at all times satisfy the requirements of the insurance company writing said policy. At either party's request, the other party shall provide the requesting party with a certificate of such policy within 15 days of the request.

Section 12.5 Limitation on Damages. EXCEPT WITH RESPECT TO THE GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT OF A PARTY, SUCH PARTY SHALL NOT BE LIABLE TO THE OTHER, WHETHER PURSUANT TO THE FOREGOING INDEMNIFICATION OBLIGATIONS OR OTHERWISE, FOR SPECIAL, EXEMPLARY OR CONSEQUENTIAL DAMAGES, INCLUDING BUSINESS INTERRUPTION OR LOST PROFITS, OR PUNITIVE DAMAGES; PROVIDED, HOWEVER, THIS EXCLUSION IS NOT INTENDED TO, NOR SHALL, EXCLUDE ACTUAL OR COMPENSATORY DAMAGES OF THE AFFECTED PARTY, INCLUDING SPECIAL, EXEMPLARY OR CONSEQUENTIAL DAMAGES OWED TO THIRD PARTIES AS A RESULT OF A THIRD PARTY CLAIM.

ARTICLE XIII. MISCELLANEOUS

Section 13.1 Notices. All notices, requests and other communications hereunder must be in writing and will be deemed to have been duly given only if delivered personally against written receipt or by facsimile transmission with answer back confirmation or mailed (postage prepaid by certified or registered mail, return receipt requested) or by overnight courier to the parties at the following addresses or facsimile numbers:

If to Voyager to:	Voyager Pharmaceutical Corporation 8540 Colonnade Center Drive Suite 409
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Raleigh, NC 27615
Attention: David Corcoran, Esq.
Facsimile: (919) 846-4881

With a copy to: Covington & Burling
1201 Pennsylvania Avenue, NW
Washington, DC 20004
Attention: Elizabeth Stotland Weiswasser, Esq.
Facsimile: (202) 778-5111

If to SBS to: Dr. Wallace B. Smith
President
Southern BioSystems, Inc.
756 Tom Martin Drive
Birmingham, AL 35211-4467
Facsimile: (205) 917-2240

With a copy to: Jean Liu
Vice President & General Counsel
DURECT Corporation
10240 Bubb Road
Cupertino, CA 95014
Facsimile: (408) 777-3577

All such notices, requests and other communications will (a) if delivered personally to the address as provided in this Section, be deemed given upon receipt, (b) if delivered by facsimile to the facsimile number as provided in this Section, be deemed given upon receipt by sender of the answer back confirmation and (c) if delivered by mail in the manner described above or by overnight courier to the address as provided in this Section, be deemed given three (3) business days after deposit with the postal service or one (1) business day after acceptance by the overnight courier service (in each case regardless of whether such notice, request or other communication is received by any other Person to whom a copy of such notice, request or other communication is to be delivered pursuant to this Section). Any party from time to time may change its address, facsimile number or other information for the purpose of notices to that party by giving notice specifying such change to the other parties hereto.

Section 13.2 Force Majeure. Neither party shall be liable for delay in delivery or nonperformance in whole or in part, nor shall the other party have the right to terminate this Agreement except as otherwise specifically provided in this Section 13.2, where delivery or performance has been affected by a condition beyond a party's reasonable control, including fires, floods, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorism, insurrections, riots, civil commotion, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any governmental authority; provided that the party affected by such a condition shall, within ten days of its occurrence, give notice to the other Party stating the nature of the condition, its anticipated duration and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no

greater scope and no longer duration than is reasonably required and the nonperforming party shall use its best efforts to remedy its inability to perform; provided, however, that in the event the suspension of performance continues for sixty (60) days after the date of the occurrence, and such failure to perform would constitute a material breach of this Agreement in the absence of such force majeure event, the nonaffected Party may terminate this Agreement immediately by written notice to the other party.

Section 13.3 Entire Agreement; Amendment. This Agreement, including the Exhibits hereto, embodies all the terms and conditions and obligations of the contract between the parties hereto and supersedes and cancels all previous agreements and understandings, whether oral or in writing, in respect of the subject matter hereof and may not be amended or modified except by an express declaration in writing signed on behalf of Voyager and SBS by duly authorized officers and referring specifically to this Agreement.

Section 13.4 Further Assurances. Each party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other party its rights and remedies under this Agreement.

Section 13.5 Successors and Assigns. The terms and provisions hereof shall inure to the benefit of, and be binding upon, Voyager, SBS and their respective successors and permitted assigns.

Section 13.6 Governing Law. This Agreement shall be governed and interpreted in accordance with the law of the State of Delaware excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

Section 13.7 Assignment. Except as expressly provided herein, neither party may, without the prior written consent of the other party, sell, transfer, assign, delegate, pledge, or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder; provided, however, that either may, without such consent, assign this Agreement and its rights and obligations hereunder to an Affiliate, to the purchaser of all or substantially all of its assets related to a Product or its business, or to its successor entity or acquiror in the event of a merger, consolidation or change in control of such. Any attempt to assign, transfer, subcontract or delegate any portion of this Agreement in violation of this Section shall be null and void. All validly assigned and delegated rights and obligations of the parties hereunder shall be binding upon and inure to the benefit of and be enforceable by and against the successors and permitted assigns of Voyager or SBS, as the case may be. In the event either party assigns or delegates its rights or obligations to another party in accordance with the terms hereof, the assignee or transferee shall assume all obligations of its assignor or transferor under this Agreement and the performance of such obligations shall be guaranteed in writing by the assignor or transferor.

Section 13.8 Waiver. Any term or condition of this Agreement may be waived at any time by the party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the party waiving such term or condition. No waiver by any party hereto of any term or condition of this Agreement, in any one or more instances, shall be deemed to be or construed as a waiver of the same or any other term or condition of this Agreement on any future occasion.

Section 13.9 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law, and if the rights or obligations of any party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never compromised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the parties herein.

Section 13.10 Independent Contractors. The status of the parties under this Agreement shall be that of independent contractors. Nothing in this Agreement is intended or shall be deemed to constitute a partnership, agency, employer, employee, or joint venture relationship between the parties. Neither party shall have the right to enter into any agreements on behalf of the other party, nor shall it represent to any Person that it has any such right or authority.

Section 13.11 Construction. Unless the context of this Agreement otherwise requires: (a) words of any gender include each other gender; (b) words using the singular or plural number also include the plural or singular number, respectively; (c) the terms "hereof," "herein," "hereby" and derivative or similar words refer to this entire Agreement; (d) the terms "Article," "Section," "Exhibit" or "clause" refer to the specified Article, Section, Exhibit or clause of this Agreement; (e) the term "or" has, except where otherwise indicated, the inclusive meaning represented by the phrase "and/or"; and (f) the term "including" or "includes" means "including without limitation" or "includes without limitation." Whenever this Agreement refers to a number of days, such number shall refer to calendar days unless business days are specified. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend, or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The language of this Agreement shall be deemed to be the language mutually chosen by the parties and no rule of strict construction shall be applied against either party hereto.

Section 13.12 Remedies. The remedies provided hereunder and under the governing law are cumulative and not exclusive.

Section 13.13 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which, taken together, shall constitute one and the same instrument.

(The remainder of this page is left blank intentionally.)

IN WITNESS WHEREOF, the parties hereto have executed this Agreement on the day and year first above written.

VOYAGER PHARMACEUTICAL
CORPORATION

SOUTHERN BIOSYSTEMS, INC.

By: /s/ David J. Corcoran

By: /s/ W. B. Smith

Name: David J. Corcoran

Name: W. B. Smith

Title: Vice President

Title: President

EXHIBIT 5.3

MANUFACTURING COSTS

"Manufacturing Costs" shall mean the sum of (i) subject to Section 5.7, materials costs necessary to Manufacture Product, including packaging thereof, (ii) direct labor and benefits, and (iii) a pro rata portion of overhead based on the relative amount of time expended by SBS on manufacturing, the total expressed as Manufacturing Cost per unit of Product manufactured.

Examples of Manufacturing Costs

- A. Materials. Includes those items which form an integral and direct part of the Product, or are necessary for its production, as well as cartons, labels, package inserts, shippers, etc.
- B. Direct Labor and Benefits. Includes labor and related payroll taxes and employment benefits spent in the actual production of the Product in accordance with all Applicable Laws and for preparing for and supporting audits and inspections under Section 5.10 and 5.11. It is that portion of basic wages, taxes and benefits which can be identified with or specifically charged to the Product.
- C. Overhead. Overhead includes all operating expenses incurred by and in support of all manufacturing cost centers and quality operations. Cost elements included are:
- Indirect labor, related payroll taxes and fringe benefits
 - Depreciation with respect to equipment and fixed assets used in connection with the Manufacture of the Product and not otherwise addressed pursuant to Section 5.7
 - Taxes (excluding taxes assessed against income)
 - Insurance
 - Rent
 - Repairs and maintenance
 - Supplies, scrap and inventory expenses
 - Utilities
 - Factory administration expenses
 - Other similar cost elements of factory overhead
 - General and administrative expense allocated to Product manufacturing centers and quality operations

Notwithstanding anything herein to the contrary, the amount included in Manufacturing Costs with respect to Manufacturing subcontracted in accordance with Section 5.1 shall be equal to the amount paid to such subcontractor.

SBS shall use Commercially Reasonable Efforts to obtain favorable prices on all materials and services (including subcontracted services) used in Manufacturing the Product. All Manufacturing Costs shall be calculated in accordance with GAAP applied on a consistent basis. SBS acknowledges and agrees that all amounts charged to SBS by its Affiliates and included in the calculation of Manufacturing Costs shall be for actual services rendered and shall be reasonable and customary and in accordance with established practice between SBS and such Affiliates.

EXHIBIT 7.1

DEVELOPMENT COSTS

“Development Costs” are the sum of: (i) actual direct costs incurred by SBS in performing its obligations under Articles II, III and IV, (ii) a pro rata portion of indirect and G&A expenses based on the relative amount of time expended by SBS on different projects, and (iii) profit (to the extent expressly agreed upon by the parties).

Examples of Development Costs

Direct Expenses

Direct research salaries and fringe benefits

Project-specific expenses and outside services in support of feasibility study and development activities, including categories such as quality assurance, engineering, and clinical testing

Project-specific supplies and equipment

Project travel and related expenses

Miscellaneous project expenses, such as shipping, literature searches, etc.

Regulatory and filing fees and maintenance payments

Indirect Expenses

Research management and indirect salaries and fringe benefits

General office and research supplies and materials

General research consulting and outside services

Facilities and cleanroom expenses

Equipment depreciation, rent, maintenance and services

Telephone and communications

Research travel and related expenses

Patent and trademark expenses

Miscellaneous indirect research expenses such as training, safety, QA expense, etc

General and Administrative Expense

Corporate management, administrative, and indirect salaries

Fringe benefits

Insurance, taxes (excluding taxes assessed against income), licenses

Marketing and business development

Telephone and communications

Equipment depreciation, rent, maintenance and services

Annual audit, accounting and legal expenses

Facilities expenses

Information services (data processing) expenses

Patent and trademark expenses

Miscellaneous general and administrative expenses

Notwithstanding anything herein to the contrary, the amount included in Development Costs with respect to subcontracted services shall be equal to (i) if the amount paid to such subcontractor is \$25,000 or less, the amount paid plus 24% of such amount as an allowance for general and administrative expenses, and (ii) if the amount paid to such subcontractor is greater than \$25,000, the amount paid plus 10% of such amount as an allowance for general and administrative expenses.

SBS shall use Commercially Reasonable Efforts to obtain favorable prices on all services (including subcontracted services) and materials used in the Feasibility and Development Activities. All Development Costs shall be calculated in accordance with GAAP applied on a consistent basis. SBS acknowledges and agrees that all amounts charged to SBS by its Affiliates and included in the calculation of Development Costs shall be for actual services rendered and shall be reasonable and customary and in accordance with established practice between SBS and such Affiliates.