## Madison, Wilton

18-01653-E

From:

Mark Edwards < medwards@biosciadvisors.com>

Sent:

Monday, January 01, 2018 8:35 PM

To:

foiapa

Subject:

**FOIA Request** 

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JAN 0 2 2018

Office of FOIA Services

I would like to request access to Exhibit 10.50 to the 3/31/13 10-K, as amended, filed by Forest Laboratories, Inc. on 6/13/2013. Confidential treatment was sought as to certain portions when initially filed with the Commission.

In the event that confidential treatment has not expired or has been extended, I further request that you send me the expiration date(s) from the relevant CT order(s) so I will know when I should resubmit my request.

Lauthorize up to \$61 in search and retrieval fees. Please send the exhibit(s) by PDF if possible.

Sincerely,

Mark

Mark G Edwards
Managing Director
Bioscience Advisors
2855 Mitchell Dr., Suite 103
Walnut Creek, CA 94598
medwards@biosciadvisors.com
925 954-1397



# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

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

Office of FOIA Services

February 15, 2018

Mr. Mark G. Edwards Bioscience Advisors 2855 Mitchell Dr., Suite 103 Walnut Creek, CA 94598

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

Request No. 18-01653-E

Dear Mr. Edwards:

This letter is in response to your request, dated January 01, 2018 and received in this office on January 02, 2018, for access to Exhibit 10.50, to the March 31, 2013 Form 10-K, as amended, and filed by Forest Laboratories, Inc. on June 13, 2013.

The search for responsive records has resulted in the retrieval of the above-requested exhibit totaling 130 pages of records that may be responsive to your request. They are being provided to you with this letter.

If you have any questions, please contact me at wadeo@sec.gov or (202) 551-8323. You may also contact me at <a href="foiapa@sec.gov">foiapa@sec.gov</a> or (202) 551-7900. You also have the right to seek assistance from Ray J. McInerney 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,

Ollie R. Wade

FOIA Research Specialist

Enclosures



# **COLLABORATION AGREEMENT**

by and between

MICROBIA, INC.

and

FOREST LABORATORIES, INC.

**September 12, 2007** 

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#### MASTER COLLABORATION AGREEMENT

This MASTER COLLABORATION AGREEMENT (the "<u>Agreement</u>") is entered into on this 12<sup>th</sup> day of September, 2007 (the "<u>Effective Date</u>"), by and among Microbia, Inc., a Delaware corporation ("<u>Microbia</u>") and Forest Laboratories, Inc. ("<u>Forest</u>"). Microbia and Forest may each be referred to herein individually as a "Party" and collectively as the "Parties."

#### **BACKGROUND**

Microbia is developing certain pharmaceutical compounds which have uses or potential uses in the treatment and prevention of disease in humans.

Forest is engaged in the research, development and commercialization of human pharmaceutical products.

Microbia and Forest desire to collaborate on the development and commercialization of Microbia's pharmaceutical compounds on the terms and conditions set forth in this Agreement.

#### **AGREEMENT**

NOW THEREFORE, in consideration of the mutual promises and covenants set forth below and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

#### 1. **DEFINITIONS.**

- 1.1. "Affiliate(s)" means, with respect to a Person, any Person that controls, is controlled by, or is under common control with such first Person. For purposes of this definition only, "control" means (a) to possess, directly or indirectly, the power to direct the management or policies of a Person, whether through ownership of voting securities or by contract relating to voting rights or corporate governance, or (b) to own, directly or indirectly, more than fifty percent (50%) of the outstanding voting securities or other ownership interests of such Person.
  - **1.2.** "Adjunctive Product" has the meaning set forth in Section 6.2.1.
- **1.3.** "API Manufacturing" means the Manufacture and supply of the active pharmaceutical ingredient of a Collaboration Compound that is included in a Product Developed and Commercialized hereunder.
- 1.4. "Applicable Laws" means all applicable statutes, ordinances, regulations, rules, or orders of any kind whatsoever of any Regulatory Authority, including, without limitation, the FD&C Act, Prescription Drug Marketing Act, Generic Drug Enforcement Act of 1992 (21 U.S.C. § 335a et seq.), and Anti-Kickback Statute (42 U.S.C. § 1320a-7b et seq.), all as amended from time to time in the Territory.

- 1.5. "Backup Compound" means [: (i) those peptides having a compound structure set forth on Schedule 1.5, (ii) peptides that are designed and synthesized by Microbia pursuant to Section 4.1.6, and (iii) other peptides designed and synthesized by Microbia which are guanylate cyclase C agonists and which Microbia has not designated or does not in good faith intend for use (primarily or as a backup) outside of the Field.]
- 1.6. "Calendar Quarter" means each of the three (3) consecutive month periods ending on March 31, June 30, September 30, and December 31.
- "Change of Control" means any of the following: (a) the sale or 1.7. disposition of all or substantially all of the assets of a Party to a Third Party, (b) the acquisition by a Third Party, other than an employee benefit plan (or related trust) sponsored or maintained by a Party or any of its Affiliates, of more than fifty percent (50%) of such Party's outstanding shares of voting capital stock (e.g., capital stock entitled to vote generally for the election of directors), (c) the appointment or election to the Board of Directors of a Party of members constituting a majority of such Board who were not appointed, approved or recommended for election by the Board of Directors as constituted immediately prior to the appointment or election of such majority, or (d) the merger or consolidation of a Party with or into another corporation, other than, in the case of (b) or (c) of this Section, an acquisition or a merger or consolidation of a Party in which holders of shares of such Party's voting capital stock immediately prior to the acquisition, merger or consolidation have at least fifty percent (50%) of the ownership of voting capital stock of the acquiring Third Party or the surviving corporation in such merger or consolidation, as the case may be, immediately after the merger or consolidation. Notwithstanding the foregoing, a Change of Control shall not be deemed to occur on account of an initial public offering, the acquisition of securities of a Party by an institutional investor, or Affiliate thereof, that acquires a Party's securities in a transaction or series of related transactions as a passive investment which does not affect the management of such Party, or a sale of assets, merger or other transaction effected exclusively for the purpose of changing the corporate domicile of a Party.
  - **1.8.** "CC" means chronic constipation.
- 1.9. "Collaboration Compound" means (i) the Initial Compound or (ii) any Backup Compound, in each case including any analogs, homologues, derivatives, salts, metabolites, esters, isomers, enantiomers, polymorphs and prodrugs of such compound. Forest's right to [include a Backup Compound as a Collaboration Compound] hereunder will expire upon [the first NDA approval by the FDA for marketing a Product in the Field], provided, however, that (i) [if such first NDA approval is subsequently revoked by the FDA and no other NDA approval by the FDA for marketing a Product then exists in the Field], then Forest's right to [include subsequent Backup Compounds shall resume and continue until the next NDA approval by the FDA for marketing a Product in the

- Field], (ii) any compound that is [a Backup Compound at the time of such first NDA approval will continue to be a Collaboration Compound notwithstanding the achievement of such first NDA approval], and (iii) with respect to a [Backup Compound described in Section 1.5(iii)] which may reasonably be expected [to have use in CC, IBS-C, OIC or any other indication] for which a Collaboration Compound is, at the time such [Backup Compound first meets the criteria of Section 1.5(iii), actively being Commercialized or Developed pursuant to this Agreement], such right shall not expire until [the fifth anniversary of the date of Commercial Launch].
- 1.10. "Collaboration Know-How" means Know-How that is invented, conceived or developed by or on behalf of either or both Parties' (or their Affiliates') employees or Third Parties acting on such Parties' behalf, in each case in the course of such Party's performance under this Agreement.
- 1.11. "Collaboration Patent Rights" means Patent Rights claiming Collaboration Know-How.
- **1.12.** "Collaboration Technology" means Collaboration Know-How and Collaboration Patent Rights, and all other intellectual property rights in any of the foregoing.
- **1.13.** "Commercial Launch" means the first commercial sale of a Product in the United States following Regulatory Approval in the United States.
- 1.14. "Commercialization" means any and all activities of using, importing, marketing, promoting, distributing, offering for sale or selling a Product, including for example pre-commercial launch market development activities conducted in anticipation of Regulatory Approval of Product, seeking pricing and reimbursement approvals for Product, if applicable, preparing advertising and promotional materials, sales force training, all interactions and correspondence with a Regulatory Authority regarding Phase IV clinical trials. Commercialization includes Promotion but does not include Development or Manufacturing. When used as a verb, "Commercialize" means to engage in Commercialization.
- **1.15.** "Commercialization Budget" means the budget approved by the JCC for conducting Commercialization pursuant to the Commercialization Plan.
- 1.16. "Commercialization Expenses" means all costs and expenses associated with Commercialization activities pursuant to the Commercialization Plan, including without limitation, FTE Costs, selling expenses, or other direct and indirect costs and expenses associated with marketing, shipping, packaging, storage and distribution of the Product for Commercialization in the Field, costs of warehousing, transportation, order entry, billing, shipping, credit and collection and other such activities in connection with Product distribution; costs for preparing

and reproducing detailing aids, Product promotional materials and other promotional materials, costs of professional education, product related public relations, relationships with opinion leaders and professional societies, market research (before and after product approval), healthcare economics studies, Phase IV clinical trials, and other similar activities directly related to the Products and, in each case, to the extent not previously deducted from gross invoiced amounts in determining Net Sales hereunder, the cost of activities related to obtaining reimbursement from payers, costs of sales and marketing data, costs associated with sales representatives and training of the sales representatives, sales meetings, details, samples, sales call reporting, work on managed care accounts, in each case to the extent not included in FTE Costs, costs related to customer service and other sales and customer service-related expenses, in each case as included in the Commercialization Plan and Commercialization Budget. Such costs may also include actual out-of-pocket costs for outside services and expenses (e.g., consultants, agency fees, meeting costs, etc.). For purposes of this definition, FTE Costs shall be charged [at the applicable FTE Rate] and the costs of sales representatives (other than the cost of acquiring samples) shall be based entirely upon the [FTE Costs as defined by Section 1.40(i) below]. Notwithstanding the foregoing, Commercialization Expenses shall not include [Manufacturing Costs and Other Out-of-Pocket Costs. In furtherance of the Parties' interest in maximizing the profitability of the collaboration, the Parties agree that the Commercialization Plan shall allocate activities to the Parties so as to avoid duplicative costs and to maximize cost efficiency to the extent practicable. In furtherance of that objective, the Commercialization Budget will include a separate amount for Commercialization support expenses, which shall be for Commercialization-related marketing, sales and administrative support costs and associated overheads not specifically attributable to activities designated under the Commercialization Plan (as used in this Section, the "Support Expenses"). Unless otherwise agreed by the Parties, the Support Expenses shall not exceed [five percent (5%) of the total Commercialization Budget before Commercial Launch and [two percent (2%)] after Commercial Launch. Each Party shall be allocated a portion of the budgeted Support Expenses in proportion to its share of Promotional activities being conducted pursuant to the Commercialization Plan (e.g. 35% to Microbia and 65% to Forest, if Microbia is performing 35% and Forest is performing 65% of the Detailing). Commercialization Expenses will include each Party's allocated portion of the Support Expenses but, without the consent of the other Party (which may be withheld in its sole discretion), Commercialization Expenses will not include any Support Expenses of a Party that exceed such Party's allocated portion of the Support Expenses.

- **1.17.** "Commercialization Plan" has the meaning set forth in Section 4.5.1.
- 1.18. "Commercially Reasonable Efforts" means those efforts and resources normally used by a Party for a product or compound owned by it or to

which it has rights of the type it has hereunder, which is of similar market potential at a similar stage in its development or product life, taking into account, without limitation, issues of safety and efficacy, product profile, the proprietary position of the product or compound, the regulatory environment and status of the compound, and other relevant scientific factors, market conditions then prevailing, including the competitive environment (but without regard to other products or compounds being developed or commercialized by such Party outside of this Agreement), profitability, the extent of market exclusivity, the cost to develop the compound or product, health economic claims, and other similar factors reasonably determined by the Party to be relevant. Without limiting the foregoing, Commercially Reasonable Efforts as it applies to the clinical development of the Collaboration Compound and Product hereunder means adherence to the activities and time lines (to the extent adherence to such activities and time lines is controllable by the Party responsible for performing such activities) set forth in the Development Plan, as may be amended from time to time based on the results of studies conducted with a Collaboration Compound and Product, and regulatory factors. "Commercially Reasonable" as used herein shall be interpreted in a corresponding manner.

- 1.19. "Commercial Year" has the meaning set forth in Section 5.2.3.
- 1.20. "Confidential Information" means, with respect to a Party, all information (and all tangible and intangible embodiments thereof), which is Controlled by such Party, is disclosed by such Party to the other Party pursuant to this Agreement, and is designated as confidential in writing by the disclosing Party whether by letter or by use of an appropriate stamp or legend, prior to or at the time any such information is disclosed by the disclosing Party to the other Party. In addition, any information which is orally, electronically or visually disclosed by a Party, or is disclosed in writing without an appropriate letter, stamp or legend, shall constitute Confidential Information if the disclosing Party, within [30 days] after such disclosure, delivers to the receiving Party a written document or documents describing the information disclosed and referencing the place and date of such oral, visual, electronic or written disclosure and the names of the person(s) to whom such disclosure was made, provided, however, that any technical information disclosed at a meeting of the JDC, JCC or any other committee established pursuant to this Agreement shall constitute Confidential Information unless otherwise specified.
- 1.21. "Control" or "Controlled" means, with respect to any intellectual property right of a Party, that the Party or its Affiliate owns or has a license to such intellectual property right and has the ability to grant access, a license, or a sublicense to such intellectual property right to the other Party as provided in this Agreement without violating an agreement with or other rights of any Third Party.
  - **1.22.** "Covered Product" has the meaning set forth in Section 6.2.2.

- 1.23. "Detail" means a one-on-one, face-to-face meeting, in an individual or group practice setting, between one or more physician prescribers and one Forest or Microbia sales representative during which product information is communicated as either the leading product (i.e., "first position") or the second product (i.e., "second position"). When used as a verb, "Detail" or "Detailing" shall mean to engage in a Detail.
  - **1.24.** "Detail Election" has the meaning set forth in Section 4.5.3.
- 1.25. "Detail Rate" as applicable to both Parties, means the [fully burdened cost of a Detail, weighted by position, reviewed annually, which costs include the cost of applicable management, initial and ongoing training, and equipment]. The "Detail Rate" shall be established based upon [Forest's standard cost accounting for such costs, consistently applied]. Each Detail shall be [weighted as a percentage of the full cost of a Detail] as follows: (i) during the [first two Years after Commercial Launch and prior to Microbia having commercially launched a second product, all Microbia Details will be allocated and compensated as primary Details, and each primary Detail of either Party shall be weighted at 66-2/3% and each Forest secondary Detail shall be weighted at 33-1/3%], and (ii) after the earlier of the [end of the first two Years after Commercial Launch or Microbia's commercial launch of a second product in the United States, each primary Detail for both Parties shall be weighted at 66-2/3% and each secondary Detail shall be weighted at 33-1/3%].
- 1.26. "Detail Reports" means a report of Details performed by a Party during the quarter covered by such report containing such information and in such format as determined by the JCC.
- 1.27. "Development" means all activities performed by or on behalf of either Party in the performance of any Development Plan for the Product in the Field in the Territory. Development shall include, without limitation, all activities related to research (including, without limitation, Post-Approval Research) preclinical testing, test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, quality assurance/quality control, clinical studies, seeking Regulatory Approval and otherwise handling regulatory affairs, statistical analysis and report writing performed pursuant to the Development Plan with respect to the Product. Development shall not include Manufacturing or Commercialization. When used as a verb, "Develop" means to engage in Development.
- **1.28.** "Development Budget" means the budget approved by the JDC for conducting Development pursuant to the Development Plan which budget will be updated and amended concurrently with the Development Plan.
- **1.29.** "Development Expense" means the costs incurred by a Party in connection with studies or activities performed under the Development Plan in

order to obtain, maintain or expand the relevant Regulatory Approval to manufacture, use or sell Product in the Field in the Territory to the extent included in the Development Budget. Development Expense shall include, without limitation, (a) all out-of-pocket costs and expenses actually incurred by Forest or Microbia in conducting such studies or activities including without limitation costs of studies on the toxicological, pharmacological, metabolic or clinical aspects of a Product conducted internally or by individual investigators or consultants and necessary for the purpose of obtaining, maintaining and/or expanding Regulatory Approval of the Product, process development, process improvement and scale-up costs, validation costs, including qualification lots, (b) the costs of internal personnel engaged in the performance of such studies or activities, including the activities described below in this Section (such costs shall be included in the Development Budget [and will be determined based on the applicable FTE Rates]), (c) all costs of developing data for Regulatory Submissions and all costs associated with making such submissions, (d) all costs related to pharmacovigilance activities, and (e) any other costs that are designated as Development Expenses herein, in each case as included in the Development Plan and the Development Budget.

- 1.30. "Development Plan" means the plan for the Development of the Collaboration Compound for Regulatory Approval prepared and approved by the JDC and as amended or updated from time to time, but in no event less frequently than once a year, in accordance with this Agreement. The initial Development Plan is attached hereto as Exhibit 1.30.
- **1.31.** "Effective Date" means the date of this Agreement first set forth above.
- "Fair Market Value" means with respect to a valuation required 1.32. by any provision hereof, the price which a willing buyer would pay, on an arm's length basis, for all rights and related intellectual property assets which comprise the assets, data or rights being valued, in light of the status of development and reasonably anticipated risks and costs of further development and the market potential for the commercialization of such assets, data or rights. In any case where Fair Market Value must be determined but is not determined by good faith negotiations between the Parties, pursuant to Section 10.3.2(b), [the determination shall be made by a Valuation Panel, whose decision shall be binding and conclusive upon the Parties. In addition, as the Parties wish to assure that Fair Market Value will be determined without regard to [inherently uncertain projections of future sales levels], Fair Market Value will be based upon [sales levels prevailing at the time Fair Market Value is being determined or, if such determination takes place prior to Commercialization of Product, shall be equal to the total investment made by the Party whose interest is being valued excluding any payment made pursuant to Section 5.1 this Agreement.
- **1.33.** "FD&C Act" means the United States Federal Food, Drug, and Cosmetic Act, as amended, and the regulations promulgated thereunder.

- **1.34. "FDA"** means the United States Food and Drug Administration or any successor agency thereto, and in Canada and Mexico shall mean regulatory authorities having similar jurisdiction.
- **1.35. "Field"** means all human diagnostic, prophylactic, and therapeutic uses of a product in any oral formulation or oral dosage form for any and all indications, including but not limited to IBS-C, CC and OIC.
- 1.36. "First Commercial Sale" means, with respect to the Product and any country of the Territory, the first sale of such Product under this Agreement for use in the Field to a Third Party in such country, after such Product has been granted Regulatory Approval for use in the Field by the competent Regulatory Authorities in such country.
- 1.37. "Forest Know-How" means (i) Know-How that Forest Controls as of the Effective Date or that comes into the Control of Forest during the Term (other than Joint Know-How or Know-How which is Microbia Know-How licensed to Forest pursuant to this Agreement) to the extent necessary or useful in the Territory to Manufacture, Develop or Commercialize any Collaboration Compound or Product, including without limitation any method of making any Collaboration Compound or Product, any composition or formulations of any Collaboration Compound or Products, or any method of using or administering any Collaboration Compound or Product, and (ii) Collaboration Know-How (other than Joint Know-How) that is invented, conceived or developed by employees of Forest or its Affiliates, or Third Parties acting on behalf of Forest or its Affiliates.
- 1.38. "Forest Patent Rights" means any Patent Right that Forest Controls as of the Effective Date or that come into the Control of Forest during the Term (other than Joint Patent Rights or Patent Rights which are Microbia Patent Rights licensed to Forest pursuant to this Agreement) to the extent such rights cover or recite any Collaboration Compound or Product, any method of making any Collaboration Compound or Product, any composition or formulations of any Collaboration Compound or Products, or any method of using or administering any Collaboration Compound or Products.
- **1.39.** "Forest Technology" means Forest's interest in (a) the Forest Know-How, and (b) the Forest Patent Rights, and all other intellectual property rights in any of the foregoing.
- 1.40. "FTE Costs" means, (i) with respect to costs associated with [Product sales representatives (collectively)] in any Calendar Quarter pursuant to this Agreement, the [Detail Rate multiplied, as applicable, by the number of primary Details, secondary Details, and, if applicable, tertiary Details, and (ii) for all other activities of a Party's employees conducted] pursuant to this Agreement in any Calendar Quarter, the [FTE Other Rate divided by four (4), multiplied by the percentage of time spent in that quarter by such employees working directly on the

Development, Commercialization or Manufacture of a Product pursuant to this Agreement].

- 1.41. "FTE Other Rate" means the [agreed upon fully burdened cost on an annual basis per employee by functional area (other than for Detailing), whether employed by Forest or Microbia, and is intended to capture salary, wages, overtime and direct benefits, other personnel costs and overheads directly associated with the activities of such employee]. The JDC and the JCC will arrange for the finance departments of each Party to discuss and agree upon appropriate FTE Other Rates for the various functional areas of this collaboration and to periodically review the appropriateness of and to adjust such rates.
- 1.42. "FTE Rate" means (i) [the Detail Rate] and (ii) [the FTE Other Rate], as applied.
- **1.43.** "GAAP" means United States generally accepted accounting principles, as in effect from time to time.
- 1.44. "Good Clinical Practice" or "GCP" means the then current standards for clinical trials for pharmaceuticals, as set forth in the FD&C Act and applicable regulations promulgated thereunder, as amended from time to time, and such standards of good clinical practice as are required by other governmental agencies in countries in which the Products are intended to be sold, to the extent such standards are not less stringent than United States GCP.
- 1.45. "Good Laboratory Practice" or "GLP" means the then current standards for laboratory activities for pharmaceuticals, as set forth in the FD&C Act and applicable regulations promulgated thereunder, as amended from time to time, and such standards of good laboratory practice as are required by other governmental agencies in countries in which the Products are intended to be sold, to the extent such standards are not less stringent than United States GLP.
- 1.46. "Good Manufacturing Practice" or "GMP" means the then current standards for manufacturing activities for pharmaceuticals, as set forth in the FD&C Act and applicable regulations promulgated thereunder, as amended from time to time, and such standards of good manufacturing practice as are required by other governmental agencies in countries in which the Products are intended to be manufactured or sold, to the extent such standards are not less stringent than United States GMP.
- **1.47. "Initial Compound"** means Microbia's proprietary guanylate cyclase C agonist polypeptide known as "Linaclotide Acetate," having the chemical structure set forth on Schedule 1.47.
- **1.48.** "**IBS-C**" means irritable bowel syndrome with the primary manifestation of constipation.

- 1.49. "Initial Development Plan" has the meaning set forth in Section 4.1.1.
  - 1.50. "JCC" has the meaning set forth in Section 3.3.
  - 1.51. "JDC" has the meaning set forth in Section 3.2.
- 1.52. "Joint Know-How" means any Collaboration Know-How that is invented, conceived or developed jointly by an employee of Microbia or its Affiliates (or a Third Party acting on any of their behalf) and an employee of Forest or its Affiliates (or a Third Party acting on any of their behalf).
- 1.53. "Joint Patent Right" means any Patent Right that claims Joint Know-How and names as the inventors one or more employees or agents of Microbia or its Affiliates together with one or more employees or agents of Forest or its Affiliates, as determined by U.S. law.
- **1.54.** "Joint Technology" means Joint Know-How, Joint Patent Rights, and all other intellectual property rights therein.
- 1.55. "Know-How" means all inventions, discoveries, data, information (including scientific, technical or regulatory information), processes, methods, techniques, materials, technology, results, analyses, laboratory, pre-clinical and clinical data, or other know-how, whether or not patentable, including without limitation pharmacology, toxicology, drug stability, manufacturing and formulation methodologies and techniques, clinical and non-clinical safety and efficacy studies, marketing studies, absorption, distribution, metabolism and excretion studies.
- **1.56.** "Manufacture," "Manufactured" or "Manufacturing" means all activities involved in the production of a Collaboration Compound or Product to be Developed and/or Commercialized under this Agreement.
- 1.57. "Manufacturing Costs" means the cost to produce the Collaboration Compound and the Product for use pursuant to the Development Plan and, as applicable, the Commercialization Plan. Manufacturing Costs will include without limitation, labor and material cost, allocable depreciation and amortization, product quality assurance/control costs, allocable facilities costs (e.g., sewer, water, property taxes), Third Party royalties, insurance, other costs borne by the Manufacturing Party for transport, customs and duty clearance and storage of the Collaboration Compound and Product, actual costs for API Manufacturing, and actual amounts paid to Third Parties for Manufacturing services (if applicable). Allocations shall be made assuming full capacity operation of the relevant facility, adjusted for changeovers in production runs, with the portion actually attributable to the Product Manufacture allocated to Manufacturing Costs. For administrative efficiency, the Parties' respective finance departments will meet from time to time to agree upon a fixed percentage of Net Sales to determine (by approximation or

other means, as mutually agreed) the Manufacturing Costs comprising distribution costs, including costs associated with shipping, storage, warehousing, transportation and distribution of the Product and billing. Such percentage shall be subject to periodic review and adjustment as necessary to assure that it continues to approximate such costs. For the avoidance of doubt, to the extent that any costs described in the preceding sentence are included in the percentage described in such sentence and deducted from Manufacturing Costs, such costs shall not be included in Commercialization Expenses. To the extent Manufacturing Costs include a Party's internal costs, such amounts shall include directly related overheads but not corporate or general overheads. All Manufacturing Costs will be determined in accordance with GAAP.

- 1.58. "Microbia Know-How" means (i) Know-How Microbia Controls as of the Effective Date or that comes into the Control of Microbia during the Term (other than Joint Know-How and Know-How which is Forest Know-How licensed to Microbia pursuant to this Agreement) to the extent necessary or useful in the Territory to Manufacture, Develop or Commercialize any Collaboration Compound or Product, including without limitation any method of making any Collaboration Compound or Product, any composition or formulations of any Collaboration Compound or Products, or any method of using or administering any Collaboration Compound or Product, and (ii) Collaboration Know-How (other than Joint Know-How) that is invented, conceived or developed by employees of Microbia or its Affiliates, or Third Parties acting on behalf of Microbia or its Affiliates.
- 1.59. "Microbia Patent Rights" means any Patent Right that Microbia Controls as of the Effective Date or that comes into the Control of Microbia during the term of this Agreement (other than Joint Patent Rights and Patent Rights which are Forest Patent Rights licensed to Microbia pursuant to this Agreement) to the extent such rights cover or recite any Collaboration Compound or Product, any method of making the Collaboration Compound or Product, any composition or formulations of the Collaboration Compound or Products, or the method of using or administering the Collaboration Compound or Product.
- **1.60.** "Microbia Technology" means Microbia's interest in (i) the Microbia Know-How, (ii) the Microbia Patent Rights, and all other intellectual property rights in any of the foregoing.
- 1.61. "Net Loss" means Net Sales [in the U.S. plus Sublicense Income in the U.S.] less Program Expenses, where the result is a negative number.
- 1.62. "Net Profit" means Net Sales [in the U S plus Sublicense Income in the U S] less Program Expenses, where the result is a positive number.
- 1.63. "Net Sales" means, on a country-by-country basis, with respect to any period for each country in the Territory, the gross amounts invoiced by Forest or its Affiliates, as applicable, to unrelated Third Parties for sales of the Product in

the Field in such country, less the following deductions to the extent included in the gross invoiced sales price for the Product or otherwise directly paid or incurred by Forest or its Affiliates with respect to the sale of the Product in such country: (i) trade, quantity or cash discounts credits, adjustments or allowances, including without limitation, those granted on account of price adjustments, billing errors, rejected goods, or damaged goods; (ii) rebates and chargebacks allowed, given or accrued (including, but not limited to, cash, governmental and managed care rebates, hospital or other buying group chargebacks, and governmental taxes in the nature of a rebate based on usage levels or sales of the Product); (iii) sales, excise, turnover, inventory, value-added, and similar taxes assessed on the sale of the Product; (iv) bad debts reserved for on the basis utilized by Forest in its branded pharmaceutical business generally or, if greater, bad debts actually written off, in each case which are attributable to sales of Product; (v) freight and insurance charges; (vi) amounts paid or credited to customers for inventory management services; and (vii) the portion of any management or administrative fees paid during the relevant time period to group purchasing organizations, wholesalers and managed care organizations to the extent determined by sales or utilization of the Product. Net Sales will be determined in accordance with GAAP. Without limiting the generality of the foregoing, sales, transfers or dispositions of Product for charitable, promotional (including samples), pre-clinical, clinical, or regulatory purposes will be excluded from Net Sales, as will sales or transfers of Product among a Party and its Affiliates.

- 1.64. "New Drug Application" or "NDA" means a New Drug Application filed with the FDA as described in 21 CFR § 314, or any corresponding application for Regulatory Approval (not including pricing and reimbursement approval) in any country or regulatory jurisdiction other than the U.S.
  - **1.65.** "OIC" means opioid induced constipation.
- **1.66.** "Operational Rights" means a Party's right to representation on the JDC and JCC, the Party's decision-making authority under the JCC and JDC, and its right to perform Detailing pursuant to the Commercialization Plan.
- 1.67. "Other Out-of-Pocket Costs" means (i) [royalties and other payments made to Third Parties in consideration for licensing or acquiring intellectual property], costs incurred in [enforcing Patent Rights pursuant to Section 8.6] of this Agreement, (ii) costs incurred in [the defense of infringement and other suits pursuant to Section 8.6, 8.7, and 8.8] of this Agreement, and (iii) costs incurred by the Parties pursuant to Section [11.1].
  - 1.68. "P&L Statement" has the meaning set forth in Section 5.4.2.
- **1.69.** "Patent Right" means any and all (a) U.S. or foreign patent applications, including, without limitation, all provisional applications,

substitutions, continuations, continuations-in-part, divisions, renewals, and all patents granted thereon, (b) all U.S. or foreign patents, reissues, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms, including, without limitation, supplementary protection certificates or the equivalent thereof, and (c) any other form of government-issued right substantially similar to any of the foregoing.

- **1.70. "Phase II"** in reference to a clinical trial means a trial defined in 21 C.F.R. 312.21(b), as may be amended from time to time, or any foreign equivalent thereto.
- 1.71. "Phase III" in reference to a clinical trial means a trial defined in 21 C.F.R. 312.21(c), as may be amended from time to time, or any foreign equivalent thereto.
- 1.72. "Phase IV" in reference to a clinical trial means a trial conducted for purposes of further characterizing and supporting the Product for marketing but not for purposes of seeking Regulatory Approval or otherwise fulfilling a requirement of a Regulatory Authority.
- 1.73. "Post-Approval Research" means ongoing research and development of a Product after such Product has received Regulatory Approval in a country of the Territory, including, without limitation, Phase IV clinical studies and clinical studies in support of indications within the Field or labeling changes for such Product within the field in such country during the term of this Agreement.
- 1.74. "Product" means any pharmaceutical product in finished oral form that contains a Collaboration Compound either as the sole active ingredient or in combination with one or more other active ingredients and all present and future oral formulations, oral dosages, and oral dosage forms thereof. For the avoidance of doubt and unless otherwise mutually agreed by the Parties, each in its sole discretion, "Product" excludes non-oral formulations, non-oral dosages and non-oral dosage forms, including without limitation intravenous and inhalable forms, including any such formulations that are combination products.
- **1.75. "Program Expenses"** means the Commercialization Expenses, Development Expenses, Manufacturing Costs, and Other Out of Pocket Costs.
- 1.76. "Promotion" means those activities normally undertaken by a pharmaceutical company's sales force to implement marketing plans and strategies aimed at encouraging the appropriate use of a particular prescription or other pharmaceutical product, including Detailing. When used as a verb, "Promote" means to engage in such activities.
- **1.77.** "Quality Agreement" means the agreement entered into pursuant to Section 4.2.3.

- **1.78.** "Reconciliation Report" has the meaning set forth in Section 5.4.4.
- 1.79. "Regulatory Approval" means the approval and authorization of a Regulatory Authority in a country necessary to develop, manufacture, distribute, sell or market a Product in that country, including pricing and reimbursement approval, where required.
- **1.80.** "Regulatory Authority" means any national (e.g., the FDA), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity in each country of the world involved in the granting of Regulatory Approval for a Product in the Territory.
- 1.81. "Regulatory Submissions" means applications for Regulatory Approval, notification and other submissions made to or with a Regulatory Authority that are necessary or reasonably desirable to Develop, Manufacture or Commercialize the Product in the Field in a particular country, whether obtained before or after a Regulatory Approval in the country. Regulatory Submissions include, without limitation, investigative new drug applications and NDAs, and amendments and supplements to any of the foregoing and their foreign counterparts, applications for pricing and reimbursement approvals, and all proposed labels, labeling, package inserts, monographs and packaging for the Product in the Territory.
  - **1.82.** "Restricted Period" has the meaning set forth in Section 6.2.1.
  - **1.83.** "Right of Reference" has the meaning set forth in Section 2.7.
- **1.84.** "Senior Management" of a Party includes, at a minimum, each of the Chief Executive Officer, Head of Research and Development, Head of Marketing, and President or Chief Operating Officer of the pharmaceutical business or division.
  - **1.85.** "Share Adjustment" has the meaning set forth in Section 5.4.1.
- 1.86. "Sublicensee" means an Affiliate or Third Party that is granted a license, sublicense, covenant not to sue or other grant of rights under this Agreement pursuant to Section 2.6 of this Agreement. "Sublicense" means an agreement or arrangement pursuant to which such a sublicense or distribution right has been granted.
- 1.87. "Sublicense Income" means all payments that Forest or an Affiliate receives from a Third Party Sublicensee in connection with any grant of rights that includes the rights granted to Forest under Section 2.2, including without limitation license fees, milestone payments, license maintenance fees, royalties and other payments, [but specifically excluding research and development funding or

reimbursement, reimbursement of costs for patent prosecution and defense, and sale of equity at fair market value].

- **1.88.** "Target Party" has the meaning set forth in Section 10.3.2(b).
- 1.89. "Technology" means Know-How and Patent Rights.
- 1.90. "Term" is defined in Section 10.1.
- **1.91.** "Territory" means the countries of North America, consisting of the United States, Canada and Mexico, and their respective territories and possessions (including Puerto Rico, irrespective of political status).
- **1.92.** "Third Part(y/ies)" means any person(s) or entit(y/ies) other than Microbia and its Affiliates and Forest and its Affiliates.
- 1.93. "Trademark" means any trademark under which the Product is sold, other than the Parties' trade names and trademarks used by the Parties to identify their companies generally.
- **1.94.** "United States" or "U.S." means the United States of America, its territories and possessions (including Puerto Rico, irrespective of political Status).
- 1.95. "Valid Claim" means a claim of an issued and unexpired Patent Right in the Territory, which claim has not been revoked or held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction, which is not appealable or has not been appealed within the time allowed for appeal, and which has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise.
- 1.96. "Valuation Panel" means a panel of [three independent Third Parties having expertise and experience in the valuation of pharmaceutical products in the Territory for human use appointed by mutual agreement of the Parties]. In the event the Parties are required by the terms hereof to select a Valuation Panel, each Party shall [select one such expert within thirty (30) days and the two experts so chosen shall select a third who shall serve as chairperson of the panel]. Each Party shall [instruct the expert chosen by it to attempt to reach agreement upon such third expert as promptly as practicable and if possible within fifteen (15) days]. The decision of [a majority of the members of the panel] entered into shall be deemed the decision of the Valuation Panel. The Parties shall instruct the Valuation Panel to reach its decision as promptly as practicable, and if possible within [thirty (30) days of selection of the third member]. The costs of this Valuation Panel shall be [covered equally (50-50%)] by the Parties.

**1.97.** "Year" means each twelve (12) month period ending December 31st.

#### 2. SCOPE OF COLLABORATION AND GRANT OF LICENSES.

- **2.1. Scope of Collaboration.** The Parties are entering into this Agreement to co-Develop the Collaboration Compound and Product in the Field and to co-Commercialize Products in the Field in the Territory.
- 2.2. License to Forest. Subject to the terms and conditions of the Agreement, Microbia hereby grants to Forest, effective on the Effective Date, a co-exclusive license (i.e., an exclusive license subject only to the rights reserved to the granting Party to the extent necessary to perform its obligations or exercise its rights hereunder), with the right to sublicense to its Affiliates or as expressly provided in Section 2.6, (i) under the Microbia Technology to Develop pursuant to the Development Plan and Manufacture the Product anywhere in the world solely for purposes of Commercialization in the Field in the Territory and to Commercialize the Product in the Field in the Territory, and (ii) under Microbia's interest in the Joint Technology to exploit any guanylate cyclase C agonists in the Field in the Territory, all in accordance with the terms of this Agreement. Notwithstanding the foregoing, Microbia reserves the right under the Microbia Technology to develop and manufacture the Product in the Territory solely for commercialization outside the Territory, provided that Microbia will disclose plans for any clinical development undertaken pursuant to this sentence in the Territory to the JDC and may not conduct any such clinical development activities in the Territory which Forest reasonably believes may adversely affect the timely clinical Development of any Product in the Territory.
- License to Microbia. Subject to the terms and conditions of the Agreement, 2.3. Forest hereby grants to Microbia (i) a royalty-free co-exclusive license (i.e., an exclusive license subject only to the rights reserved to the granting Party to the extent necessary to perform its obligations or exercise its rights hereunder), with the right to freely sublicense subject to Section 2.6, under the Forest Technology and Forest's interest in the Joint Technology to the extent necessary for Microbia to Develop and Manufacture the Product anywhere in the world and to Commercialize the Product in the Field in the Territory and to otherwise exercise its rights and perform its obligations under this Agreement, all in accordance with the terms of this Agreement, and (ii) a perpetual, royalty-free, exclusive license, with the right to freely sublicense subject to Section 2.6, (x) under Forest's interest in the Forest Technology to develop, manufacture and commercialize the Collaboration Compound and Product in the Field outside of the Territory and to develop (subject to the proviso in the final sentence of Section 2.2 above) and manufacture the Product in the Territory for purposes of commercialization in the Field outside the Territory and (y) under Forest's interest in the Joint Technology to exploit any guanylate cyclase C agonists (other than Collaboration Compounds) outside the Field in the Territory and outside the Territory in any field of use.
- **2.4. Restrictions**. Microbia will not exercise or otherwise exploit the Joint Technology or the Forest Technology in the Field with respect to the Territory and Forest will not exercise or otherwise exploit the Joint Technology or the Microbia Technology in the Field with respect to the Territory, in each case except pursuant to this Agreement. In addition,

neither Party will develop or commercialize a Collaboration Compound in the Territory, or outside the Field, whether within or outside the Territory, in each case including by means of licenses to or collaborations with Third Parties, except pursuant to or as otherwise permitted by the terms of this Agreement.

- **2.5. Joint Technology.** Each Party hereby grants the other Party a world-wide, non-exclusive, perpetual, royalty-free, fully paid up, freely sublicenseable right and license under its interest in the Joint Technology to exploit compounds that are not guanylate cyclase C agonists anywhere in the world, without compensating or accounting to the other Party.
- 2.6. Sublicensing. Except as provided in Section 2.5, Forest will have no right, except upon prior written consent of Microbia, which consent may not be unreasonably withheld, to grant sublicenses to Third Parties under the rights granted to Forest under this Agreement, and provided that [neither Party will have the right to sublicense its rights under this Agreement with respect to activities constituting Development or Commercialization for the U.S.,] except upon prior written consent of the other Party, which may be withheld in such Party's sole discretion. Any sublicenses granted by either Party hereunder shall be consistent with the terms of this Agreement. In addition, each Party shall require any licensee or Sublicensee, whether within or outside the Territory, of Technology with respect to the Collaboration Compound or the Product, to cross-license or otherwise transfer or convey back to the granting Party all Technology which such licensee or Sublicensee may develop or acquire so that any of such Technology will be Controlled by the granting Party for purposes and to the extent of the licenses to the other Party provided by Sections 2.2 and 2.3 above.
- **Right of Reference.** Microbia hereby grants to Forest a "Right of Reference," as 2.7. that term is defined in 21 C.F.R. § 314.3(b) in the Field in the Territory to the data included in the Collaboration Technology to the extent necessary or useful to Manufacture, Develop or Commercialize a Collaboration Compound or Product, and Forest hereby grants to Microbia (and Microbia's partners) such a Right of Reference to the data included in the Collaboration Technology to the extent necessary or useful to Manufacture, Develop or Commercialize a Collaboration Compound or Product in the Field throughout the world, in each case subject to the terms and conditions of this Agreement. Each Party shall provide a signed statement to this effect, if requested by the other, in accordance with 21 C.F.R. § 314.50(g)(3) solely, in the case of a request by either Party with respect to the Territory, for the limited purpose of such Party exercising its rights or performing its obligations under this Agreement. In addition, Microbia will provide Forest with advance copies of any substantive Regulatory Submissions made in the European Union or Japan reasonably in advance of submission to a Regulatory Authority for Forest's review, and shall provide Forest with an opportunity to comment, or make suggestions, which comments or suggestions will not be unreasonably rejected to the extent related to issues potentially affecting the Field or the Territory. Any such copies of [Regulatory Submissions] shall be Confidential Information of Microbia. The Parties agree that Microbia may make available to its collaborators and partners with respect to Collaboration Compounds or Products outside the Territory any Regulatory Submissions made in the Territory pursuant to this Agreement.

- **2.8.** No Other Rights. No rights, other than those expressly set forth in this Agreement are granted to either Party hereunder, and no additional rights shall be deemed granted to either Party by implication, estoppel or otherwise. All rights not expressly granted by either Party to the other hereunder are reserved.
- Section 365(n). All rights and licenses granted under or pursuant to this 2.9. Agreement by Forest or Microbia are, and will otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, will retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code, the Party hereto that is not a party to such proceeding will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and same, if not already in their possession, will be promptly delivered to them (i) upon any such commencement of a bankruptcy proceeding upon their written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement, or (ii) if not delivered under (i) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject party.

#### 3. DECISION MAKING AND DISPUTE RESOLUTION.

- 3.1. Overview. During the Term, management and oversight for all of the activities of the Parties related to the Development and Commercialization of the Product in the Field in the Territory will be provided by the committees set forth below and elsewhere in this Agreement. The Parties anticipate that the committees would perform the functions ascribed to them hereunder; provided, however, that the functions and operations of the committees may be altered from time to time during the Term by the mutual agreement of the Parties to appropriately address ongoing requirements with respect to the Development and Commercialization of the Product. In addition to the committee meetings, the Parties anticipate that members of Senior Management from Forest and Microbia will meet periodically as necessary or appropriate during the Term (and in any event at least once per Year) in order to review significant issues and developments in the Development and Commercialization of a Collaboration Compound or the Product.
- **3.2. Joint Development Committee.** The Parties shall establish a joint development committee ("<u>JDC</u>") that will be responsible for overseeing the Development of the Product in the Field in the Territory, and will serve as a forum for exchanging data, information and Development strategy regarding the Product.
- 3.2.1. <u>Membership</u>. The JDC will consist of three (3) senior representatives from each Party. Microbia and Forest will each designate a co-chair for the JDC. The co-chairs will be responsible for calling meetings and setting the agenda (which shall include a list of all participants expected at a meeting) and circulating such agenda at least five (5) days prior to each meeting and distributing minutes of the meetings within thirty (30) days

following such meeting, but will not otherwise have any greater power or authority than any other member of the JDC. JDC members shall have such expertise as appropriate to the activities of the JDC from time to time and the JDC shall invite personnel of the Parties having formulation, manufacturing, commercial, marketing and other expertise to participate in discussions of the JDC from time to time as appropriate to assist in the activities of the JDC.

- 3.2.2. Responsibilities. The JDC's responsibilities will include, among others: (i) preparing and approving the Development Plan and Development Budget for the Product, and any amendments to such plan, (ii) approving (or establishing procedures to approve) protocols for pre-clinical or clinical studies, (iii) making modifications to and performing quarterly monitoring of progress of pre-clinical and clinical studies and proposing additional studies for the Product, (iv) monitoring the Parties' compliance with the budgets for Development Expenses, (v) reviewing and commenting on Regulatory Submissions relating to the Product, and (vi) facilitating the exchange of all data, information, material or results relating to the development of the Product. The JDC may appoint additional committees as desired.
- 3.2.3. Meetings. During Development, the JDC will meet at such frequency as shall be established by the Parties (but not less frequently than four (4) times per year). Meetings of the JDC shall alternate between the offices of the Parties, unless otherwise agreed upon by the members of the JDC, or may be held telephonically or by video conference. Meetings of the JDC shall be effective only if at least one representative of each Party is in attendance or participating in the meeting. Members of the JDC shall have the right to participate in and vote at meetings by telephone. Each Party shall be responsible for expenses incurred by its employees and its members of the JDC in attending or otherwise participating in JDC meetings. Each Party shall use reasonable efforts to cause its representatives to attend the meetings of the JDC. If a representative of a Party is unable to attend a meeting, such Party may designate an alternate to attend such meeting in place of the absent representative.
- 3.2.4. <u>Minutes and Agendas</u>. The minutes of each JDC meeting shall provide a description in reasonable detail of the discussions held at the meeting and a list of any actions, decisions or determinations approved by the JDC. Minutes of each JDC meeting shall be approved or disapproved, and revised as necessary, at the next meeting.
- **3.3. Joint Commercialization Committee.** The Parties will establish a joint commercialization committee ("<u>JCC</u>") that will oversee the Commercialization of the Product in the Field in the Territory. The JCC will coordinate selling and marketing efforts under the Commercialization Plan and will serve as a forum regarding Product Commercialization in the Field in the Territory.
- 3.3.1. <u>Membership</u>. The JCC will consist of three (3) senior representatives from each Party. Microbia and Forest will each designate a co-chair for the JCC. The co-chairs will be responsible for calling meetings and setting the agenda for and distributing minutes of the meetings, but will not otherwise have any greater power or authority than any other member of the JCC. JCC members shall have such expertise as appropriate to the activities of the JCC from time to time and the JCC shall invite personnel of the Parties having

development, formulation, manufacturing, financial and other expertise to participate in discussions of the JCC from time to time as appropriate to assist in the activities of the JCC.

- 3.3.2. Responsibilities. The JCC will be responsible for, among other things, (i) establishing the strategy for the Commercialization of the Product in the Field in the Territory, (ii) developing and approving the Commercialization Plan and Commercialization Budget for the Product in the Field in the Territory, as well as updating the Commercialization Plan on an annual basis to reflect materially changed circumstances, and amending the Commercialization Plan from time to time as appropriate, (iii) subject to the specific terms and conditions hereof, allocating responsibilities under the Commercialization Plan to the Parties in accordance with the Parties' abilities to perform such activities in the most efficient and cost effective manner, (iv) overseeing the implementation of the strategy for Commercializing the Product in the Field in the Territory (including strategies related to regulatory approvals, reimbursement, advertising and promotion, brand integrity, sales, and launch sequence as set forth in the Commercialization Plan), (v) providing input to the JDC regarding the target product profile for the Product and making recommendations regarding changes to the same, (vi) developing, reviewing and approving the annual marketing plans for the Product in the Field in the Territory, (vii) reviewing the Parties' marketing and promotional activities to ensure that such activities are consistent with the Commercialization Plan, (viii) preparing, approving and amending the Commercialization Budget, (ix) establishing usage instructions for the Trademarks and (x) monitoring the Parties' compliance with the Commercialization Budget.
- 3.3.3. Meetings. The JCC will meet at such frequency as shall be established by the Parties (but not less frequently than four (4) times per year prior to launch and during the first five years of Commercialization). Meetings of the JCC shall alternate between the offices of the Parties, unless otherwise agreed upon by the members of the JCC, or may be held telephonically or by video conference. Meetings of the JCC shall be effective only if at least one representative of each Party is in attendance or participating in the meeting. Members of the JCC shall have the right to participate in and vote at meetings by telephone. Each Party shall be responsible for expenses incurred by its employees and its members of the JCC in attending or otherwise participating in JCC meetings.
- 3.3.4. <u>Minutes and Agendas</u>. The minutes of each JCC meeting shall provide a description in reasonable detail of the discussions held at the meeting and a list of any actions, decisions or determinations approved by the JCC. Minutes of each JCC meeting shall be approved or disapproved, and revised as necessary, at the next meeting.
- 3.4. Joint Responsibilities of the JDC and JCC. In addition to the independent JDC and JCC meetings, the JDC and the JCC shall coordinate to hold joint meetings as appropriate to discuss issues which are relevant to both Development and Commercialization, including without limitation, in order to: (i) establish the target product profile for the Product (including [indications for which the Product will be Developed and Commercialized, key labeling claims required for commercial success of the Product] given the competitive environment, and any other [key product features and benefits which will be used to Develop or support a promotional message or reimbursement status] for the Product), (ii) discuss development of the Product for

[additional indications and alternative delivery forms] and (iii) discuss development of improvements in [formulation, presentation and other features of Products considered desirable for life cycle management and maximizing sales] of the Products throughout the Territory. Such joint meetings may be held by videoconference, teleconference or in person and any decisions required to be taken shall be submitted to the JDC or JCC for resolution in accordance with the terms hereof. Each Party shall be responsible for expenses incurred by its employees and its Committee members in attending or otherwise participating in joint meetings of the JDC and JCC.

- **3.5. Other Committees.** The Parties may establish other committees or subcommittees as the Parties deem appropriate.
- **3.6.** Elevation and Dispute Resolution. Each Party's representatives on any committee will collectively have one vote on all matters that are within the responsibility of such committee. The members of each committee will use reasonable efforts to reach consensus on all decisions. In the event of a deadlock regarding a particular issue on which the members of a committee cannot reach consensus, such issue will be resolved as follows:

In the event that the members of the JDC or JCC are unable to agree on a particular issue, such issue shall be referred, in the case of a matter governed by the JDC, to the Parties' respective Chief Scientific Officers or their designees, and in the case of a matter governed by the JCC, to the Parties' respective heads of marketing or their respective designees, for attempted resolution of such matter. In the event such individuals are unable to resolve such issue within 30 days, such issue shall be referred to the Chief Executive Officers of each Party or their designees for resolution. Subject to the remaining provisions of this Section, (i) all matters relating to Development, including, without limitation, amendments and modifications to the Development Plan, must be determined by consensus of the Parties and (ii) [with respect to Commercialization matters, in the event the Chief Executive Officers of Forest and Microbia are unable to reach consensus, Forest shall have the final decision-making authority. The Parties will from time to time identify a panel of mutually agreed consultants with expertise in pharmaceutical development to assist the JDC in the resolution of development issues and, upon the request of either Party, such experts shall be requested to advise as to Development issues where consensus cannot be reached, with the advice of such experts not to be unreasonably rejected. Notwithstanding the foregoing, if a matter for which consensus cannot be reached is addressed by the then current Development Plan, then such Development Plan and the activities required thereunder will control despite any inability of the Parties to reach consensus. Finally, in connection with any Commercialization decisions [made by Forest in accordance with its authority pursuant to this Section establishing or significantly adjusting the Commercialization Budget, [Forest will provide to and discuss with Microbia] all supporting data and analyses [possessed by Forest with respect to such decision] and shall [make such decisions reasonably and with due regard to Microbia's input].

## 4. DEVELOPMENT, REGULATORY, COMMERCIALIZATION.

#### 4.1. Development

- 4.1.1. <u>Product Development Plan</u>. The initial Development Plan for the Product in the Field is set forth in <u>Exhibit 1.30</u> (the "<u>Initial Development Plan</u>"). The JDC will direct, coordinate and manage the Development of the Product in the Field, according to the Development Plan. The following provisions shall apply with respect to the Development of Products:
  - (a) The Development Plan for the Product will include, among other things, the indications in the Field for which the Product is to be Developed and other exploratory indications in the Field for which the Product may be developed, critical activities to be undertaken, certain timelines, Go/No Go decision points and relevant decision criteria and certain allocations of responsibilities between the Parties for the various activities to be undertaken under the Development Plan. The Development Plan will also include a Development Budget, as mutually agreed by the Parties. Neither Party will be required, in any Calendar Quarter, to make any Development investment in excess of the [120%] of the amount designated to such Party in the Development Budget for such Calendar Quarter. During the Term, the JDC will amend the Development Plan on an ongoing basis as necessary.
  - (b) The JDC will oversee the allocation and assignment of Development activities in the Development Plan between the Parties. Such allocations and assignments shall be consistent with the more specific provisions set forth in <u>Schedule 4.1.1</u>.
  - (c) The Parties will use Commercially Reasonable Efforts to implement and conduct the Development activities assigned to them pursuant to the Development Plan, in accordance with Applicable Laws.
- 4.1.2. <u>Future Development Activities</u>. Recommendations regarding whether to jointly Develop a Product for new indications or new formulations shall be made by the JDC. Such approved additional joint Development activities shall become part of the Development Plan.
- 4.1.3. Non-Development Plan Activities. All Development work proposed to be undertaken by a Party and not provided for in the then current Development Plan shall be submitted for consideration by the JDC. In the event the JDC determines not to include such proposed Development activities in the Development Plan, which determination will be made within [one hundred and twenty (120)] days of its receipt of such proposal, and neither Party has any reasonable objection from a Development, Commercialization or regulatory point of view to the conduct of such Development activities, the Party proposing such Development activities shall have the right to conduct such activities [at its sole cost and expense]. In such event, the other Party [shall not have the right to use or a Right of Reference to the data and

Know-How arising from such Development activities and, [in the calculation of Net Profits and Net Losses, amounts attributable, if any, to incremental sales of or incremental costs associated with the Product arising from such Development activities shall not be included but the profits and losses associated therewith shall be allocated to the Party undertaking such Development activities. Without limiting the generality of the foregoing, incremental Commercialization Expense incurred by a Party in connection with [its Promotion of a Product or for an indication, as applicable, [which the Party has elected not to Develop pursuant to this Section shall be for the account of the Party that undertook Development pursuant to this Section, and the Party providing such [Promotional activities shall be reimbursed for any such incremental expense. Notwithstanding anything to the contrary in this Section, the Party [initially declining to perform such Development activities may subsequently acquire the right to use the associated data and Know-How and to participate in Net Profits and Net Losses without the adjustment described above, provided it agrees to [pay fifty percent (50%) of all Development Expenses incurred in such Development activities (whether incurred prior to or after such Party's election to participate), plus a premium of fifty percent (50%) of its share of such Development Expenses incurred prior to such election to participate.

- 4.1.4. <u>ESAs</u>. The Parties will, from time to time after the Effective Date, agree on the level of activity of external scientist affairs personnel needed to adequately educate physicians regarding the use of the Product (each an "<u>ESA</u>"). Upon at least 60 days prior notice to Forest, Microbia may elect to provide up to thirty-five percent (35%) of the ESA activity. The activities of ESAs shall comply with all Applicable Laws and ethical policies, including all compliance and ethics policies maintained by Forest.
- 4.1.5. Reports of Development Activities. Each Party shall report on Development activities undertaken by such Party in accordance with Development Plan in connection with meetings of the JDC, including by providing a reasonably detailed summary of all results, data and material inventions, if any, obtained from such activities. In addition, each Party shall, at its own expense, make appropriate scientific and regulatory personnel available to the other Party, either by telephone or in person as the Parties may mutually agree, as reasonably required to keep the other Party informed of Development activities.
- 4.1.6. Backup Compounds. From time to time pursuant to this Section 4.1.6, Forest may request that Microbia synthesize peptides which are guanylate cyclase C agonists designed for the diagnostic, prophylactic or therapeutic treatment of IBS, CC or OIC in the Field. Upon such request, Microbia will use Commercially Reasonable Efforts to [design and synthesize such peptides]. All costs incurred in such [design and synthesis] will be included as [Development Expenses] hereunder. Any such [peptides so requested, designed and synthesized will be added as backup compounds for Development and Commercialization pursuant to this Agreement ("Back-Up Compounds")]. Forest's right to request the [design and synthesis of Back-Up Compounds] pursuant to this Section 4.1.6 will expire upon [the first NDA approval by the FDA for marketing a Product in the Field], provided that if such [NDA approval is subsequently revoked by the FDA and no other NDA approval by the FDA for a Product then exists in the Field], then Forest's right to request the [design and synthesis of Back-Up Compounds pursuant to this Section 4.1.6 shall resume and continue until the next

NDA approval by the FDA for marketing a Product in the Field]. Notwithstanding the foregoing, Forest may not request that [Microbia design and synthesize more than two (2) such peptides] in a request made pursuant to this Section 4.1.6 during any [six-month] period. Upon the addition of any such [Backup Compound as a Collaboration Compound], the JDC will determine the appropriate Development activities, if any, to be undertaken with respect to such Collaboration Compound, [whether in lieu of Development of the Initial Compound or in addition to the Development of the Initial Compound]. Subject to Section 4.1.1(c), neither Party shall have any operational or financial obligations with respect to the [Development of Backup Compounds] except to the extent set forth in a Development Plan approved by the JDC.

4.1.7. Third Party Comparative Information. In the event either Party from time to time possesses objective Third Party information (for example, from a qualified contract research organization) which indicates that specific Development activities can be achieved in a more cost-effective manner than as provided by the Development Plan or as such plan is then being implemented, the JDC shall review and give due regard to such information with the obligation of achieving such cost savings to the extent attainable without negatively impacting conduct of the Development Plan, including, without limitation, the timing and quality of Development activities.

### 4.2. Regulatory Matters.

- 4.2.1. <u>Responsibility For Regulatory Interactions</u>. Regulatory strategy for the Product and all decision-making with respect thereto shall be determined by the Parties through the JDC. The Parties shall use Commercially Reasonable Efforts to obtain in a timely manner Regulatory Approvals with respect to the Product to the extent contemplated by the Development Plan. Certain agreed [allocations of regulatory responsibilities between the Parties] are set forth on <u>Schedule 4.1.1</u> hereto. The costs incurred by the Parties in carrying out their assigned responsibilities pursuant this Section 4.2.1 [shall be included as <u>Development Expenses</u>].
- 4.2.2. Regulatory Cooperation. The Party responsible for carrying out a regulatory activity pursuant to this Agreement or having primary FDA contact responsibility will keep the other Party reasonably informed regarding the status and progress of such activity, including without limitation, providing the other Party with advance notice of all meetings scheduled with a Regulatory Authority (including notice within twenty-four (24) hours of a request for a meeting received from a Regulatory Authority) involving a Regulatory Submission, and an agenda and an invitation to attend such meetings, providing the other Party with a copy of all substantive written correspondence from a Regulatory Authority involving a Regulatory Submission, notifying the other Party of all oral substantive correspondence from a Regulatory Authority involving a Regulatory Submission, and providing such other Party with an advance draft of each proposed Regulatory Submission sufficiently in advance of providing the submission to the Regulatory Authority (and in any event no less than seven days in advance) to enable the other Party to have a meaningful opportunity to provide comments on the content of such submission and no such submission (including any NDA) shall be submitted for filing with the Regulatory Authority without the mutual agreement of the Parties,

such consent not to be unreasonably withheld or delayed. Furthermore, the Parties shall agree in advance on all substantive written communications with and, to the extent permitted by Applicable Law, shall both have the right to participate in all meetings and oral communications with Regulatory Authorities in the applicable countries in the Territory to the extent related to the Product. All costs and expenses incurred by the Parties in carrying out its allocated regulatory activities pursuant to this Agreement will be included as Development Expenses or Commercialization Expenses, depending on the activities to which such costs relate.

- 4.2.3. Quality Agreement. Within ninety (90) days after the Effective Date, the Parties will enter into an agreement governing the quality standards required under this Agreement or by Third Party vendors (including Third Parties performing API Manufacturing).
- 4.2.4. <u>Clinical Trial Data</u>. The JDC will coordinate the maintenance of separate databases for clinical trial data being developed by each Party, including the merger of such databases as may be appropriate, or will assign responsibility for the maintenance of a master database for all clinical trial data. All costs to maintain such databases (including internal FTE costs) will be included as Development Expense.
- 4.3. Adverse Events. Within ninety (90) days after the Effective Date, the Parties will enter into a pharmacovigilence agreement, which upon such execution will be attached as an exhibit hereto and hereby incorporated into this Agreement by reference (the "Pharmacovigilence Agreement"). The Parties will comply with the provisions of such agreement. Forest will maintain and will be the recognized holder of a global safety database for Adverse Event reports related to Collaboration Compound and Product received by either Party. Forest will respond to safety inquiries regarding the Product in the Field in the Territory. All costs incurred by the Parties in performing its obligations under the Pharmacovigilence Agreement and maintaining the Adverse Event database will be included as Development Expenses.
- 4.4. Manufacture and Supply of Products. The Parties shall establish a manufacturing and supply chain working group to oversee Manufacturing (including API Manufacturing of the Collaboration Compound). The Parties shall collaborate through such working group (with Microbia taking the lead) to oversee API Manufacturing of Collaboration Compound for clinical supplies and for commercial distribution and sale as contemplated by the Development Plan and Commercialization Plan. All Manufacturing responsibilities for API Manufacturing shall be allocated to the Parties or Third Parties as mutually agreed by the Parties; provided, however, that nothing herein shall prevent Microbia from contracting with any Third Parties for the supply of API for commercialization outside the Territory. Forest shall be responsible for all Manufacturing other than for API Manufacturing for the Field with respect to the Territory. Unless otherwise mutually agreed, any supply agreement (including agreements for process or scale-up development) with a Third Party pertaining to the supply of Product for sale in the Territory shall be [entered into by both Parties, provided that Forest shall only be included as a signatory to a supply agreement] to the extent such agreement pertains to

supply of Product for commercialization in the Territory. The Parties will perform all Manufacturing activities allocated to them in accordance with GCP, GLP and GMP.

- **4.5. Commercialization in the Territory.** Microbia and Forest shall commercialize the Products in accordance with the Commercialization Plan as follows:
- 4.5.1. Commercialization Plan. The JCC shall approve a strategic commercialization plan for the Product in the Field in the Territory (the "Commercialization Plan") which sets forth, among other things, (a) a multi-year marketing strategy that includes plans for market research, health economics, pricing and reimbursement, medical affairs and value added initiatives, (b) a multi-year communications strategy that includes plans for public relations, conferences and exhibitions and other external meetings, internal meetings and communications, publications and symposia, internet activities and core brand package, (c) a multi-year strategy for Phase IV studies and lifecycle management activities (d) a high level operating plan for the implementation of such strategies on an annual basis, including without limitation, information related to product positioning, core messages to be communicated, share of voice requirements and pricing strategies, all as developed and approved by the JCC, (e) a level of detailing activity that would be Commercially Reasonable for a company comparable to Forest for a primary care product having similar market potential in the Territory, (f) a Commercialization Budget, and (g) all other activities to be conducted in connection with the Commercialization of the Product in the Field in the Territory. The Commercialization Plan will be updated at least once a year.
- 4.5.2. Commercialization Activities. Forest will use Commercially Reasonable Efforts to Commercialize Products in the Field throughout the Territory, subject to compliance by Microbia with its obligations hereunder to the extent such compliance would be material to Forest's performance of its Commercialization obligations hereunder. In addition, the Parties will use Commercially Reasonable Efforts to conduct the Commercialization activities assigned to them by the JCC pursuant to the Commercialization Plan, including the performance of Detailing in accordance therewith. In conducting the Commercialization activities the Parties will comply with all Applicable Laws, applicable industry professional standards and compliance policies of Forest which have been previously furnished to Microbia, as the same may be updated from time to time and provided to Microbia. Forest will assist Microbia in training sales representatives in such standards. Neither Party shall make any claims or statements with respect to the Product that are not strictly consistent with the Product labeling and the sales and marketing materials approved for use pursuant to the Commercialization Plan. As between the Parties, Forest will book all sales of Products and will have the sole responsibility for the sale, invoicing and distribution of the Product in the Territory].

#### 4.5.3. Promotion Participation.

(a) Microbia Detailing. Microbia will have the right to have a national sales force distributed geographically within the U.S. in a manner similar to Forest's sales representatives, [with the opportunity to call on similarly deciled physicians]. Upon notice to Forest in accordance with this Section 4.5.3,

Microbia may elect to provide between twenty percent (20%) and thirty-five percent (35%) of the aggregate annual number of weighted Details (*i.e.*, weighted in the same manner as set forth in the definition of Detail Rate) to be provided pursuant to the Commercialization Plan ("Detail Election"). Microbia will provide its Detail Election notice for each Product as follows: For the period beginning upon Commercial Launch of a Product and ending on the completion of the then current Forest fiscal year, Microbia will provide notice of its Detail Election [within thirty (30) days] after acceptance by the FDA of the NDA for the Product, and for each Forest fiscal year thereafter, Microbia will provide its Detail Election at least [two hundred and seventy (270) days] prior to the beginning of such Forest fiscal year. The Details elected by Microbia pursuant to a Detail Election will be included in the Commercialization Plan and will represent the number of weighted Details allocated to Microbia during the applicable year.

- Detailing Requirements. Each Party's Detailing activities shall be governed by the terms of this Agreement and the provisions set forth on Schedule 4.5.3 attached hereto. Each Party will promptly notify the other Party at any time that it appears reasonably likely that it will not be able to substantially achieve required levels of Detailing over any significant period or in any significant area. Following any such notice, the Parties will meet and confer in good faith to develop a plan to achieve such required levels of Detailing] as promptly as practicable, including through the [utilization of the other Party's sales force personnel as reasonably required to achieve the required levels of Detailing. For the avoidance of doubt, but without limiting either Parties remedies otherwise available under this Agreement, (i) if Microbia elects not to provide Details or elects to provide less than thirty-five percent (35%) of the Detailing [Forest may perform such Details], and (ii) if Forest does not provide all of the Details it is required to provide pursuant to the Commercialization Plan, then [Microbia may perform such Details]. If one Party's sales force personnel are [utilized to fulfill Details allocated to the other Party] under the Commercialization Plan, the Parties will cooperate to [transition Detailing efforts from the Party that is unable (or in the case of Microbia, elects not) to perform to the other Party as promptly as practicable in light of the need to assure a smooth transition of Detailing activities]. Except to the extent provided in Section 1.25, each Party shall be [assigned first and second position Details in the same proportion as its total Detailing responsibilities for the applicable period. As an example of the application of the previous sentence: If Microbia elects to provide thirty-five percent (35%) of the total Details provided by both Parties under the Commercialization Plan, Microbia will be allocated thirty-five percent (35%) of the [total primary Details] provided by both Parties and thirty-five percent (35%) of the [total secondary Details] provided by both Parties
- 4.5.4. <u>Termination of Microbia Promotion Efforts</u>. Microbia may terminate its promotional efforts under the Agreement at any time, effective upon <u>[twelve (12)]</u> months written notice to Forest. If Microbia exercises the foregoing right, Microbia shall provide such

transition activities as and for such period as Forest may reasonably request, including, without limitation, arranging for meetings between members of the Microbia sales force and sales representatives of Forest, to assure a smooth transition of marketing efforts. Forest may terminate Microbia's rights to participate in the promotion of the Product, effective upon sixty (60) days written notice to Microbia, in the event that the Detail Reports for at least [two (2)] consecutive Calendar Quarters indicate that Microbia's Detailing has not achieved at least eighty percent (80%) of the Detailing to be performed by Microbia as set forth in the Commercialization Plan (as to number or position of Details) for each such Calendar Quarter, upon the failure by Microbia to achieve at least eighty percent (80%) of the Detailing to be performed by Microbia as targeted by the Commercialization Plan (as to numbers or portions of Details) in the aggregate over a period of [four] consecutive Calendar Quarters, or upon the continuing material failure by Microbia to provide Details in accordance with the standards set forth herein and on Schedule 4.5.3, unless in any such case, during such [sixty (60)] day period Microbia develops and implements a program of increased Detailing which provides, to Forest's reasonable satisfaction, assurance that Detail shortfalls (including failures to achieve Detailing standards) will not again occur. Except to the extent of the remedies provided by this Section, the failure of Microbia to meet the number of Details required under the Commercialization Plan shall not be deemed a material breach under this Agreement and shall not give Forest a right to terminate this Agreement or Microbia's other Operational Rights and responsibilities hereunder.

- 4.5.5. Additional Collaboration of Marketing Forces. From time to time upon reasonable advance notice by Microbia, Forest will arrange for a reasonable number of Microbia's marketing personnel to work with Forest's personnel for mutually agreed periods, taking into account space availability and subject to reasonable restrictions on access and activities of Microbia's personnel while at Forest's facilities. Such arrangements shall be aimed at fostering collaboration between the Parties marketing forces for the purpose of more efficiently and effectively Commercializing the Product in the Field under this Agreement. Forest shall provide reasonable advance notice to Microbia of any significant marketing events (e.g., annual brand team or Commercialization Plan meetings) to enable Microbia to arrange for members of its staff to be available for such meetings.
- 4.6. Phase IV and Publication Strategy. Neither Party will undertake, or permit its Affiliates, licensees or Sublicensees to undertake, whether within or outside the Territory, any pre-clinical or clinical marketing studies of the Product, including, without limitation, Phase IV Studies, but excluding any studies required for registration or imposed by a Regulatory Authority in a country within the Territory or, in the case of studies by Microbia, in any territory, without consultation with both Parties and, in the case of studies by Forest, consultation with Microbia and Microbia's collaborators and partners, as applicable, in the development and commercialization of the Product outside the Territory, and in each case due consideration will be given to comments received from the other Party or its collaborators and partners. With respect to studies required for registration purposes or imposed by a Regulatory Authority outside of the Territory, [Forest will be afforded the reasonable opportunity to review and provide comments with respect to any such proposed studies] as provided by Section 2.7.

The Parties will also coordinate worldwide publication strategy involving the Product and activities involving the Product related to scientific conferences inside and outside the Territory, including through delegation to appropriate working groups of the Parties. Each Party shall be afforded the opportunity to review and approve any scientific paper or presentation with respect to the Product proposed for publication, presentation or distribution by the other Party or its Affiliates and licensees or Sublicensees and shall have no more than [ten (10) days] to complete such review and approval or such shorter period as may reasonably be required by applicable publication deadlines promptly communicated to such Party. The Party proposing publication or presentation shall not unreasonably reject comments furnished by the other Party, will comply with the other Party's request to delete references to its Confidential Information in any such publication or presentation and will delay publication for such reasonable period requested by the other Party to permit the filing of patent applications concerning any Forest Technology, Microbia Technology or Joint Technology disclosed in material proposed for such publication or presentation. In no event will Confidential Information of a Party be published without the consent of such Party.

The Parties will coordinate the disclosure of the initiation and results of clinical studies performed pursuant to the Development Plan or clinical studies performed by either Party's licensees or Sublicensees with respect to any Collaboration Compound or Product, whether within or outside of the Territory, to the extent required by law or best industry practices; provided that all proposed disclosures and publications will be submitted for expeditious review by the JDC and due regard will be given to the comments of each Party, the maintenance of confidentiality of Confidential Information of each Party and allowing time for intellectual property registrations. Nothing set forth herein shall be deemed to limit or restrict either Party from disclosing the results of clinical trials (whether performed by the Parties or by Third Parties) to the extent required by law or best industry practices. The Parties intend that the provisions of this Section 4.6 shall apply to the Parties and their respective Affiliates, licensees and Sublicensees.

#### 5. CONSIDERATION.

**5.1. Upfront Payments.**, Forest shall make the following payments to Microbia: (i) Fifty Million Dollars (\$50,000,000) within fifteen (15) days after the Effective Date as an upfront, non-creditable, non-refundable fee, and (ii) Twenty Million Dollars (\$20,000,000) within ten (10) days following January 15, 2008 as a non-creditable, non-refundable license fee.

#### 5.2. Milestones.

5.2.1. <u>Development Milestones</u>. As additional consideration for the rights granted to Forest pursuant to Section 2.2, Forest will pay Microbia the following non-creditable, non-refundable amounts within [thirty (30) days] after the first occurrence of each of the following events:

EVENT	MILESTONE PAYMENT

EVENT	MILESTONE PAYMENT
Dosing the first patient in the first Phase III clinical trial for purposes of obtaining Regulatory Approval	\$[ <u>20,000,000</u> ]
in the United States using a Product in treating or preventing IBS-C	\$25,000,000 equity investment as further described in Section 5.2.2 below.
Dosing the first patient in the first Phase III clinical trial for purposes of obtaining Regulatory Approval in the United States using a Product in treating or preventing CC	\$[ <u>10,000,000</u> ]
Acceptance of the first NDA by a Regulatory Authority in the United States for use of a Product in treating or preventing IBS-C	\$[ <u>10,000,000</u> ]
Acceptance of the first NDA by a Regulatory Authority in the United States for use of a Product in treating or preventing CC	\$[ <u>10,000,000</u> ]
The first Regulatory Approval of an NDA by a Regulatory Authority in the United States for use of a Product in treating or preventing IBS-C	\$[ <u>60,000,000</u> ]
The first Regulatory Approval of an NDA by a Regulatory Authority in the United States for use of a Product in treating or preventing CC	\$[ <u>25,000,000</u> ]

Notwithstanding the preceding, in the event Forest provides notice of termination of this Agreement to Microbia pursuant to Section 10.2.2 prior to the occurrence of a milestone event set forth above, Forest shall not be obligated to make any such or subsequent Development Milestone payment (including the equity investment referred to above and further described under 5.2.2 below), provided that if Forest provides notice of termination within [thirty (30)] days of the achievement of the first NDA approval Milestone for either CC or IBS-C based upon Forest's determination that such approval provides for labeling or is subject to conditions which would make it not Commercially Reasonable to Commercialize the Product as contemplated by this Agreement, in lieu of paying the associated NDA approval Milestones, Forest shall be obligated to pay Microbia \$[12,500,000] within [thirty (30)] days of such approval, unless Microbia has determined at that time not to Commercialize the Product, or to discontinue such Commercialization, in which case no such payment or further payment shall be required pursuant to this Section, and provided that notwithstanding the foregoing, Forest shall otherwise continue to perform all of its obligations under this Agreement until any such termination becomes effective in accordance with this Agreement. Forest shall make any such determination in a Commercially Reasonable manner.

5.2.2. Equity Investment. Subject to Microbia obtaining the necessary consents and approvals by its shareholders, and notwithstanding the thirty (30) day period for payment set forth in Section 5.2.1, within forty-five (45) days of the initiation of the first Phase III clinical trial in the Territory using a Product in treating or preventing IBS-C, Forest shall purchase from Microbia for an aggregate purchase price of \$25,000,000 pursuant to a Stock Purchase Agreement (as defined below) two million, eighty three thousand, three hundred and thirty four (2,083,334) shares of Series G Preferred Stock at a per share purchase price equal to \$12.00 per share. The terms of such purchase shall be (i) for a purchase prior to an initial public offering by Microbia, in accordance with a stock purchase agreement in form and substance (including the associated charter amendments and exhibits, the "Stock Purchase Agreement") as attached hereto at Schedule 5.2.2(i), or (ii) for a purchase after an initial public offering by Microbia, in accordance with a stock purchase agreement having the terms set forth on the term sheet attached hereto as Schedule 5.2.2(ii) and prepared in customary form and having other customary terms and conditions applicable to such investments. Microbia will use reasonable efforts to seek waivers of preemptive rights from other Microbia shareholders in connection with the issuance of the shares, and in any event, will not sell or issue Series G Preferred Stock to any person other than in connection with an exercise by Microbia shareholders of such preemptive rights. The number of shares of Microbia common stock into which the Series G Preferred Stock is convertible (or the number of shares of Microbia common stock which would be purchased pursuant to subsection (ii) above) shall be subject to adjustment from and after the Effective Date (x) in accordance with the provisions governing adjustment for stock splits, stock dividends, reclassifications and reorganizations included in the form of Stock Purchase Agreement set forth on Schedule 5.2.2(i), and (y) until the closing of Microbia's initial public offering in accordance with the terms of all of the anti-dilution provisions included in the form of Stock Purchase Agreement set forth on Schedule 5.2.2(i), notwithstanding that such shares of Series G Preferred Stock will be issued at a date subsequent to the Effective Date.

5.2.3. <u>Sales Milestones</u>. Forest will pay Microbia the following non-creditable, non-refundable amount within [thirty (30) days] after the first occurrence of the following event:

EVENT	MILESTONE PAYMENT
End of first Commercial Year in which aggregate annual Net Sales of Products in the United States are at least \$1,000,000,000, if such Commercial Year occurs within the first eight (8) Commercial Years of Commercialization.	\$[ <u>100,000,000</u> ]
End of first Commercial Year in which aggregate annual Net Sales of Products in the United States are at least \$1,000,000,000, if such Commercial Year occurs after the first eight Commercial Years but within the first ten (10) Commercial Years of	\$[ <mark>80,000,000</mark> ]

Commercialization, provided that at such time, the	
Product is expected to have at least four (4) years of	
legal or regulatory market exclusivity in the United	
States.	

For purposes of this Section 5.2.3 and Section 5.4.1 below, a "Commercial Year" shall refer to the twelve (12) month period beginning on the first day of the first full month following the Commercial Launch of the Product and each consecutive twelve (12) month period thereafter.

Royalties. Forest will pay to Microbia royalties based on the aggregate annual 5.3. Net Sales of Products sold by Forest, its Affiliates or its Sublicensees in the Field in all countries in the Territory other than the United States (the "Royalty Territory") at a rate of Isixteen percent (16%) of such Net Sales; provided that, for the purposes of determining Net Sales under this Section 5.3, Net Sales shall be determined as the gross amounts invoiced by Forest, its Affiliates or Sublicensees less the deductions and subject to the other provisions set forth in the definition of "Net Sales" in this Agreement. Within forty (45) days after the beginning of each Calendar Quarter beginning with the Calendar Quarter in which the first sale is made in the Royalty Territory following receipt of Regulatory Approval in such country, Forest shall deliver to Microbia a report setting forth for the previous Calendar Quarter the following information on a Product-by-Product and country-by-country basis: (a) the gross sales and Net Sales of each Product in the Royalty Territory, (b) the number of units sold by Forest, its Affiliates or Sublicensees, (c) the basis for any adjustments to the royalty payable for the sale of each Product, (d) the royalty due hereunder for the sales of each Licensed Product, and (e) the applicable exchange rate as determined in accordance with this Agreement. The total royalty due for the sale of Products during such Calendar Quarter shall be remitted at the time such report is made.

#### 5.4. Program Expenses.

5.4.1. Allocation of Program Expenses and Net Profit. Each Party shall account for Program Expenses in accordance with GAAP and its standard cost accounting practices, in each case as consistently applied. Each Party shall pay fifty percent (50%) of all Program Expenses incurred by the Parties in connection with Development and Commercialization of Products in the U.S. during the Term, and each Party shall have the right to receive fifty percent (50%) of the Net Profit and shall bear fifty percent (50%) of the Net Loss in the U.S., as applicable; provided, however, that if a Party [provides fewer Details in a particular year than it is required to provide pursuant Section 4.5.3 (and, in the case of Microbia, if Microbia for any reason, including by reason of its Detail Election or termination of its right to perform Details in accordance herewith, performs fewer than thirty-five percent (35%) of the Details required by the Commercialization Plan)], such Party's share of Net Profits will be reduced for such year by [the number of Details not provided multiplied by the Detail Rate] (the "Share Adjustment"), provided, however, that [as to Microbia, with respect to the first two (2) Commercial Years, no Share Adjustment shall be made, and with respect to the succeeding two (2) Commercial Years, only 50% of the Share Adjustment shall be made].

Forest will bear all Program Expenses incurred with respect to countries in the Royalty Territory.

- 5.4.2. Payment of Expenses: Profit and Loss Statements. Subject to reconciliation as provided in Section 5.4.4 and the handling of costs for Development and Commercialization outside the U.S. pursuant to Section 5.4.1, the Party initially incurring Program Expenses shall be responsible for and pay for all such Program Expenses so incurred. in the case of Microbia, with respect to the U.S., and in the case of Forest with respect to the Territory. Subject to the limitations set forth in Section 5.4.3, each Party shall maintain the books and records referred to in Section 5.4.5 and shall accrue all Program Expenses (and, in the case of Forest, Net Sales) in accordance with the terms and conditions hereof and in accordance with GAAP and each Party's standard cost accounting, in each case as consistently applied. Within thirty (30) days of the end of each Calendar Quarter each Party shall submit to the other a written report reflecting the accrual of Program Expenses and Net Sales, which report shall be accompanied by reasonable supporting documentation or description (each a "P&L Statement"). Upon the request of either Party from time to time, the Parties' respective finance departments, coordinated by the JDC or JCC as appropriate, will discuss any questions or issues arising from the P&L Statements, including the basis for the accrual of specific Program Expenses.
- 5.4.3. Expense Limitations. Additionally, the Parties hereby agree that efforts of the employees of a Party or its Affiliates in performing its activities hereunder shall be accrued and reported at the applicable FTE Rate then in effect, provided, however, that only those efforts that are contemplated by the applicable Development Plan or Commercialization Plan, or are Manufacturing activities approved hereunder, shall be so accrued and reported. All payments made by a Party to a Third Party in connection with the performance of its activities under the Development Plan, the Commercialization Plan or its Manufacturing shall be accrued and reported [at such Party's actual out-of-pocket cost]. Expenses incurred by each Party for [equipment, materials and supplies utilized] in performing its activities under the Development Plan or Commercialization Plan [shall not be separately accrued, except for those expenses incurred by a Party (with the prior written consent of the JDC or JCC, as applicable or as expressly provided for in the Development Plan or Commercialization Plan), in the purchase or making of equipment, materials or supplies to the extent not included in the FTE Rate (other than common laboratory supplies, e.g., pipettes, test tubes, Petri dishes, reagents, and the like) to the extent to be used [in connection with the performance of such Party's activities under the Development Plan (e.g., laboratory animals, Collaboration Compound, Product, placebo supplies, etc.), or Commercialization Plan or Manufacturing, which expenses shall be accrued at such Party's [actual out-of-pocket expense incurred in purchasing or making such equipment, materials or supplies].
- 5.4.4. <u>Reconciliation</u>. As soon as practicable after the receipt by Forest of Microbia's P&L Statement, but in any event within thirty-nine (39) days after the end of each Calendar Quarter, Forest shall prepare a reconciliation report, accompanied by reasonable supporting documents and calculations, which reconciles the amounts accrued and reported in each Party's P&L Statement during such Calendar Quarter pursuant to Section 5.4.1

(Allocation of Program Expenses), including, without limitation, making any necessary adjustments for prior period manufacturing cost variances allocable to Products utilized in Development or Commercialization, and the share of the Parties' aggregate Program Expenses and their Net Profits and Net Losses (determined based on such Program Expenses), to be allocated to each of the Parties for such Calendar Quarter in accordance with Section 5.4.1 (the report setting forth the foregoing reconciliation being the "Reconciliation Report"). Based on the Reconciliation Report, there shall be a cash settlement between the Parties no later than sixty (60) days after the end of each Calendar Quarter. In the event any payment is made after the date specified in the preceding sentence, the paying Party shall increase the amount otherwise due and payable by adding interest as provided in Section 5.5 compounded monthly from the date such additional amount should have first been paid, provided however, no Party shall be charged interest hereunder to the extent it is late in making payment as a result of the other Party's delay in reporting its Program Expenses or other information required to prepare such reconciliation. In the event a Party fails to make payment as required pursuant to this Section 5.4.4, amounts due may be offset against any which are payable to such Party hereunder, provided, however, amounts being contested in good faith pursuant to appropriate proceedings hereunder will not be subject to offset.

5.4.5. Records and Audits. During the term of this Agreement, each Party shall keep and maintain accurate and complete records showing the expenses incurred by it in performing its activities under the Development Plan and Commercialization Plan and Manufacturing during the three preceding calendar years, which books and records shall be in sufficient detail such that Program Expenses, Net Profits, Net Losses and royalties can accurately be determined. Upon fifteen (15) days prior written notice from a Party (the "Auditing Party"), the other Party (the "Audited Party") shall permit an independent certified public accounting firm of nationally recognized standing, selected by the Auditing Party and reasonably acceptable to the Audited Party, to examine the relevant books and records of the Audited Party and its Affiliates as may be reasonably necessary to verify the P&L Statement submitted by the Audited Party in accordance with Section 5.4.2 and the accuracy of the reconciliation report prepared in accordance with Section 5.4.4 (Reconciliation). An examination by a Party under this Section 5.4.5 shall occur not more than once in any calendar year and shall be limited to the pertinent books and records for any calendar year ending not more than thirty-six (36) months before the date of the request. The accounting firm shall be provided access to such books and records at the Audited Party's facility(ies) where such books and records are normally kept and such examination shall be conducted during the Audited Party's normal business hours. The Audited Party may require the accounting firm to sign a standard non-disclosure agreement before providing the accounting firm access to the Audited Party's facilities or records. Upon completion of the audit, the accounting firm shall provide both Microbia and Forest a written report disclosing whether the reports submitted by the Audited Party are correct or incorrect and the specific details concerning any discrepancies. No other information shall be provided to the Auditing Party. If the accountant determines that, based on errors in the reports so submitted, the Reconciliation Report is incorrect, the Parties shall promptly revise the Reconciliation Report and any additional amount owed by one Party to the other shall be paid within thirty (30) days after receipt of the accountant's report, along with interest at the annual interest rate as provided in Section 5.5, compounded monthly

from the date of the audit report, provided, however, that no such interest shall be payable if the errors leading to the Reconciliation Report being incorrect were in the P&L Statement provided by the Party to receive such additional amount. Additionally, if the accountant determines that the P&L Statement submitted by the Audited Party overstate the Audited Party's expenses by more than ten percent (10%), the Audited Party shall reimburse the Auditing Party for the expenses incurred by the Auditing Party in conducting the audit.

- 5.4.6. Taxes and Withholding. All payments under this Agreement shall be made without any deduction or withholding for or on account of any tax unless such deduction or withholding is required by applicable laws or regulations. As of the Effective Date, the Parties believe that, under applicable laws and regulations, withholding of taxes on payments made under this Section 5.4 is not required provided, however, that if due to any change in the applicable laws or regulations, or either Party's interpretation thereof, withholding is required, the provisions of this Section shall govern. If the paying Party is so required to deduct or withhold, such Party shall (i) promptly notify the other Party of such requirement, (ii) pay to the relevant authorities the full amount required to be deducted or withheld promptly upon the earlier of determining that such deduction or withholding is required or receiving notice that such amount has been assessed against the other Party, (iii) promptly forward to the other Party an official receipt (or certified copy) or other documentation reasonably acceptable to the other Party evidencing such payment to such authorities and cooperate in any other manner as reasonably necessary to assist the other Party in obtaining any refund it is entitled to in connection therewith.
- 5.4.7. <u>Currency</u>. All amounts payable and calculations hereunder shall be in United States dollars. As applicable, Net Sales and any Development Expenses incurred by either Party shall be translated into United States dollars in accordance with the paying Party's customary and usual currency conversion procedures, consistently applied. If, due to restrictions or prohibitions imposed by national or international authority, payments cannot be made as provided in this Section 5, the Parties shall consult with a view to finding a prompt and acceptable solution, and the paying Party shall deal with such monies as the other Party may lawfully direct at no additional out-of-pocket expense to the paying Party.
- 5.4.8. <u>Confidentiality</u>. All financial information of a Party which is subject to review under this Section 5.4 shall be deemed to be Confidential Information subject to the provisions of Section 6.1, and such Confidential Information shall not be disclosed to any Third Party or used for any purpose other than verifying payments to be made by one Party to the other hereunder, provided, however, that such Confidential Information may be disclosed to Third Parties only to the extent necessary to enforce a Party's rights under this Agreement.
- 5.5. Interest. Any payment under this Section 5 that is more than [forty-five (45)] days past due shall be subject to interest at an annual percentage rate of [the Prime Rate] (as published in the "Money Rates" table of the Eastern Edition of The Wall Street Journal during period such amount is overdue) [plus 0.5%] if a Party does not make payment within thirty (30) days of its receipt of notice that such amount is past due. Likewise, any overpayment that is not refunded within [forty-five (45)] days after the date such overpayment was made shall thereafter be subject to interest at an annual percentage rate of [the Prime Rate] (as published in the

"Money Rates" table of the Eastern Edition of The Wall Street Journal during period such amount is overdue) [plus 0.5%], provided, however, that if the overpayment is due to errors in reports provided by the overpaid Party, such interest shall accrue from the date the overpayment was made. Notwithstanding the preceding, if a Party contests any amounts due hereunder in good faith and promptly notifies the other Party of such dispute, interest shall not accrue as to amounts being so contested until [forty-five (45)] days following the presentation of such notice to the other Party.

#### 6. MUTUAL COVENANTS.

#### 6.1. Confidentiality.

- 6.1.1. Confidential Information. Except to the extent expressly permitted by this Agreement and subject to the provisions of Sections 6.1.2 and 6.1.3, at all times during the Term and for [five (5)] years following the expiration or 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, consultants or representatives who have a need to know such information (collectively, "Recipients") to perform such Party's obligations hereunder and (b) shall not use Confidential Information of the Disclosing Party directly or indirectly for any purpose other than performing its obligations hereunder. The Receiving Party shall be liable for any breach by any of its Recipients of the restrictions set forth in this Agreement.
- 6.1.2. 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 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 or fiduciary duty 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 or restriction 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 any restriction imposed by the Disclosing Party on disclosure, whether such restriction is by contract, fiduciary duty or by operation of law; or

- (e) that the Receiving Party can demonstrate by competent evidence was independently developed by the Receiving Party without any reference to Confidential Information.
- 6.1.3. <u>Authorized Disclosure</u>. Each Party and its Recipients may disclose Confidential Information to the extent that such disclosure is made in response to a valid order, governmental inquiry or request (each an "order") of a court of competent jurisdiction or other Agency, as applicable; 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 or 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 Agency 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 that is legally required to be disclosed in such response to such court or governmental order.
- 6.1.4. <u>Notification</u>. 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.
- 6.1.5. Destruction of Confidential Information. Upon the expiration or earlier termination of this Agreement, the Receiving Party shall (a) destroy all tangible embodiments of Confidential Information of the Disclosing Party, including any and all copies thereof, and those portions of any documents, memoranda, notes, studies and analyses prepared by the Receiving Party or its Recipients that contain, incorporate or are derived from such Confidential Information and provide written certification of such destruction to the Disclosing Party in a form reasonably acceptable to the Disclosing Party, provided that the legal department of the Receiving Party shall have the right to retain one copy of any such tangible embodiments for archival purposes, provided such copy shall continue to be maintained on a confidential basis subject to the terms of this Agreement, and (b) immediately cease, and shall cause its Recipients to cease, use of such Confidential Information as well as any information or materials that contain, incorporate or are derived from such Confidential Information.
- 6.1.6. <u>Use of Name and Disclosure of Terms</u>. Each Party shall keep the existence of, the terms of and the transactions covered by this Agreement confidential and shall not disclose such information to any other Person through a press release or otherwise, or mention or otherwise use the name, insignia, symbol, trademark, trade name or logotype of the other Party or its Affiliates in any manner without the prior written consent of the other Party in each instance (which shall not be unreasonably withheld). The restrictions imposed by this Section shall not prohibit either Party from making any disclosure that is required by Applicable Law, rule or regulation or the requirements of a national securities exchange or another similar regulatory body including disclosing such information in any clinical trial database maintained by or on behalf of a Party. Further, the restrictions imposed on each Party under this Section 6.1.6 are not intended, and shall not be construed, to prohibit a Party from

identifying the other Party in its internal business communications, provided that any Confidential Information in such communications remains subject to this Section 6.1.6.

6.1.7. Remedies. The Parties acknowledge and agree that the restrictions set forth in Section 6.1 are reasonable and necessary to protect the legitimate interests of the Parties and that neither Party would have entered into this Agreement in the absence of such restrictions, and that any breach or threatened breach of any provision of Section 6.1 will result in irreparable injury to the other Party for which there will be no adequate remedy at law. In the event of a breach or threatened breach of any provision of Section 6.1 by a Party, the other Party shall be authorized and entitled to obtain from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, specific performance and an equitable accounting of all earnings, profits and other benefits arising from such breach, which rights shall be cumulative and in addition to any other rights or remedies to which such Party may be entitled in law or equity. The breaching Party agrees to waive any requirement that the nonbreaching Party (i) post a bond or other security as a condition for obtaining any such relief and (ii) show irreparable harm, balancing of harms, consideration of the public interest or inadequacy of monetary damages as a remedy. Nothing in this Section 6.1.7 is intended, or shall be construed, to limit the Parties' rights to equitable relief or any other remedy for a breach of any provision of this Agreement.

#### 6.2. Restrictions.

6.2.1. Covered Products Restrictions. From the date of Commercial Launch of the Product in the United States through the [fifth] anniversary of the date of such Commercial Launch (the "Restricted Period"), neither Party will commercialize, either independently or directly or indirectly with any Third Party, any Covered Products (as defined below) in the Field in the Territory, either alone or in combination with any other therapeutically active substance, other than the Products in accordance with the terms of this Agreement. After the Restricted Period, if either Party elects to commercialize a Covered Product in the Territory during any period that the Product continues to be Promoted as a brand name pharmaceutical product pursuant to this Agreement, it shall do so through a separate sales force and separate marketing personnel to the extent required to assure to the reasonable satisfaction of the other Party the independence of the Commercialization of the Product. In addition, except to the extent provided by the following sentence and [unless Forest is able to demonstrate to Microbia's reasonable satisfaction that such commercialization will not adversely affect the Promotion of the Product by Forest, in the event Forest elects to commercialize a product (other than a Covered Product) in the Territory during the Restricted Period which is indicated for any indication as to which the Product has received Regulatory Approval or as to which the Product is then in active Development, all decisions relating to Commercialization shall require the consensus of the Parties through the balance of the Restricted Period during which such commercialization continues. Notwithstanding the preceding, [the commercialization by Forest of pharmaceutical products containing the compounds known as dexloxiglumide or milnacipran (other than in combination with another Covered Product) shall not be limited or restricted by any of the provisions of this Section. In addition, nothing in this Section 6.2.1 or 6.2.2 shall restrict a Party from commercializing a product (an "Adjunctive Product") which

such Party demonstrates to the reasonable satisfaction of the other Party will be utilized as a concomitant therapy or in a patient population for which the Product will not be a first line of therapy. A Party proposing to market an Adjunctive Product during the Restricted Period will discuss in good faith with the other Party the potential participation of such other Party in the marketing of such Adjunctive Product to the extent the same can be accomplished on a Commercially Reasonable basis and the proposing Party has the right to do so.

- 6.2.2. [Acquisition of Covered Products]. In the event that either Party or any of its Affiliates signs a definitive agreement or otherwise enters into or consummates any transaction (a "Covered Product Transaction") during the Restricted Period by operation of which such Party would acquire rights in, by ownership, license or other contractual rights to promote, distribute or otherwise engage in any Development or Commercialization activities with respect to the Territory with respect to any compound which, as a material contributor to its efficacy, enhances intestinal fluid secretion or transit and is indicated for the diagnosis, prophylaxis or treatment of IBS-C, CC, OIC, or any other indication for which a Product is then being Commercialized in the Territory pursuant to this Agreement (each a "Covered <u>Product</u>"), then such Party shall, within [nine (9) months] from the [closing of such Covered Product Transaction, divest or terminate all of its rights to such Covered Product with respect to the Territory, and during such [nine-month period, the Development and Commercialization of such product by such Party would not be in violation of any provision of this Section 6.2 so long as no personnel involved in the Development or Commercialization of the Product under this Agreement engage in such activities with respect to the Covered Product. To effect such a divestiture, the divesting Party must either (i) convey all of its rights in the Covered Product in the Territory to a Third Party, or (ii) grant a license (exclusive as to such Party and its Affiliates) to a Third Party for the right to develop, make, use and sell such Covered Product in the Territory. Notwithstanding the preceding, [a product shall not be deemed a Covered Product to the extent indicated for an indication as to which the JDC has determined not to pursue Development and for which the Product is not being Commercialized].
- **6.3. Compliance with Law.** Each Party hereby covenants and agrees to comply with all Applicable Laws applicable to its activities connected with the Development, Manufacture and Commercialization (as applicable) of Products. Without limiting the generality of the foregoing:
- 6.3.1. <u>Patient Information</u>. Each Party agrees to abide by all laws, rules, regulations, and orders of all applicable supranational, national, federal, state, provincial, and local governmental entities concerning the confidentiality or protection of patient identifiable information and/or patients' protected health information, as defined by U.S. C.F.R. Part 160 or any other applicable legislation, in the course of their performance under this Agreement.
- 6.3.2. Export Controls. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries which may be imposed upon or related to Microbia or Forest from time to time. Each Party agrees that it shall not export, directly or indirectly, any technical information acquired from the other Party pursuant to this Agreement or any Products using such technical

information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity.

- 6.3.3. <u>Debarment</u>. Each Party agrees that it shall not use, in any capacity, in connection with any of its obligations to be performed under this Agreement any individual who has been debarred under the FD&C Act or the Generic Drug Enforcement Act.
- Nonsolicitation of Employees. During the Term of this Agreement and for a period of one year thereafter, each Party agrees that neither it nor any of its Affiliates shall recruit, solicit or induce any employee of the other Party that is involved in the activities conducted pursuant to this Agreement to terminate his or her employment with such other Party and become employed by or consult for such other Party, whether or not such employee is a full-time employee of such other Party, and whether or not such employment is pursuant to a written agreement or is at-will. For purposes of the foregoing, "recruit", "solicit" or "induce" shall not be deemed to mean (a) circumstances where an employee of one Party initiates contact with the other Party or any of is Affiliates with regard to possible employment, or (b) general solicitations of employment not specifically targeted at employees of a Party or any of its Affiliates, including responses to general advertisements. In addition, during the Term of this Agreement and for a period of one year thereafter, neither Party shall hire or employ any such employee of the other Party (including personnel who were employees of such other Party within a period of [one year] or less from the date of the proposed hiring or employment) without the prior written consent of such other Party, unless such other Party had previously terminated the employment of such former employee.
- **6.5. Standstill Agreement.** Except as provided in Section 5.2.2, during the Term (the "<u>Standstill Period</u>"), neither Forest nor any of its Representatives (as defined below) (collectively the "<u>Forest Related Parties</u>") will, in any manner, directly or indirectly:
  - 6.5.1. make, effect, initiate, directly participate in or cause
  - (a) any acquisition of beneficial ownership of any securities of Microbia or any securities of any Affiliate of Microbia, if, after such acquisition, the Forest Related Parties would beneficially own more than ten percent (10%) of the outstanding common stock of Microbia; or
  - (b) any acquisition of all or substantially all of the assets of Microbia or of any Affiliate of Microbia; provided this subsection (b) shall not apply to the acquisition by the Forest Related Parties of a license or other rights to Microbia assets or technology under terms negotiated by the Parties; or
  - (c) any tender offer, exchange offer, merger, business combination, recapitalization, restructuring, liquidation, dissolution or extraordinary transaction involving Microbia or any Affiliate of Microbia, or involving any securities or assets of Microbia or any securities or assets of any Affiliate of Microbia; or

- (d) any "solicitation" of "proxies" (as those terms are used in the proxy rules of the Securities and Exchange Commission) or consents with respect to any securities of Microbia; or
- 6.5.2. form, join or participate in a Group with respect to the beneficial ownership of any securities of Microbia; or
- 6.5.3. act, alone or in concert with others, to seek to control the management, board of directors or policies of Microbia; or
- 6.5.4. take any action that might require Microbia to make a public announcement regarding any of the types of matters set forth in clause "(a)" of this sentence; or
- 6.5.5. agree or offer to take, or encourage or propose (publicly or otherwise) the taking of, any action referred to in clause "(a)", "(b)", "(c)" or "(d)" of this sentence; or
- 6.5.6. assist, induce or encourage any other person to take any action of the type referred to in clause "(a)", "(b)", "(c)" or "(d)" of this sentence; or
- 6.5.7. enter into any discussions, negotiations, arrangement or agreement with any other person relating to any of the foregoing; or
- 6.5.8. request or propose, publicly or to shareholders (except in a shareholder's capacity as Chief Executive Officer of Microbia) of Microbia or its Affiliates, that Microbia or any of Microbia's Representatives (as defined below) amend, waive or consider the amendment or waiver of any provision set forth in this Section 6.5.

Notwithstanding the foregoing, the provisions of this Section 6.5 shall not apply to (i) the exercise by any of the Forest Related Parties of any rights available to shareholders generally pursuant to any transaction described in Section 6.5.1(a) above, provided that such Forest Related Party has not then either directly or as a member of a Group made, effected, initiated or caused such transaction to occur, or (ii) any activity by any of the Forest Related Parties after Microbia or any other Third Party unrelated to any of the Forest Related Parties has made any public announcement of its intent to solicit or engage in any transaction of the type referred to in this Section 6.5.1(a) above, provided however, with respect to subpart (ii), if any of the Forest Related Parties or such Third Party terminates or announces its intent to terminate such transaction and such Forest Related Party (A) has not previously made any public announcement of its intent to solicit or engage in any transaction of the type referred to in this Section 6.5.1(a) above, or (B) in the event that such public announcement has been made by any of the Forest Related Parties, such Forest Related Party has terminated or announced its intent to terminate such transaction, then the provisions of this Section 6.5 shall again be applicable.

For purposes of this Section, "<u>Representatives</u>" of a Party will be deemed to include each person or entity that is or becomes (i) an Affiliate of such Party, or (ii) an officer, director, employee, partner, attorney, advisor, accountant, agent or representative of such Party or of any

of such Party's Affiliates, provided such person is acting on behalf of such Party or such Party's Affiliate. "Group" means two or more persons acting as a partnership, limited partnership, syndicate or other group for the purpose of acquiring, holding or disposing of securities of Microbia.

#### 7. REPRESENTATIONS AND WARRANTIES.

- **7.1.** Representations and Warranties of Each Party. As of the Effective Date, each of Forest and Microbia hereby represents and warrants to the other Party hereto as follows:
  - (a) it is a corporation or entity duly organized and validly existing under the laws of the state or other jurisdiction of its incorporation or formation;
  - (b) the execution, delivery and performance of this Agreement by such Party has been duly authorized by all requisite corporate action and does not require any shareholder action or approval;
  - (c) it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder;
  - (d) the execution, delivery and performance by such Party of this Agreement and its compliance with the terms and provisions does not and shall not conflict with or result in a breach of any of the terms and provisions of or constitute a default under (i) a loan agreement, guaranty, financing agreement, agreement affecting a product or other agreement or instrument binding or affecting it or its property; (ii) the provisions of its charter or operative documents or bylaws; or (iii) any order, writ, injunction or decree of any court or governmental authority entered against it or by which any of its property is bound; and
  - (e) it has the full right, power and authority to grant all of the right, title and interest in the licenses granted to the other Party under this Agreement.
- **7.2.** Additional Representations and Warranties of Microbia. Microbia hereby represents and warrants to Forest that as of the Effective Date:
  - (a) Microbia has the sole right, title and interest in and to the Microbia Patent Rights listed in <u>Schedule 7.2(a)</u> to this Agreement
  - (b) Microbia is not subject to any agreement with a Third Party that includes a royalty or similar payment obligation to, or other restriction or limitation in favor of, such Third Party (including, for this purpose, to current or former officers, directors, employees, consultants or personnel of Microbia or any predecessor) with respect to its rights to practice the Microbia Technology;

- (c) No Microbia Patent Rights are subject to, or were developed pursuant to any funding agreement with any government or government agency, except as provided in <u>Schedule 7.2(c)</u> to this Agreement;
- (d) Microbia is not in breach of any material provisions of any agreements with Third Parties relating to the Microbia Patent Rights and all of such agreements are set forth on <u>Schedule 7.2(d)</u>;
- (e) To its Knowledge, the manufacture, use, sale, offer for sale and import of the Initial Compound in the Field in the Territory does not infringe any Valid Claim of a Third Party; and
- (f) Microbia has not received any written or oral claim of ownership, inventorship or patent infringement from any Third Party (including without limitation, by current or former officers, directors, employees, consultants, or personnel of Microbia or any predecessor) with respect to the Microbia Technology, and Microbia is not aware of any reasonable basis for any such claim.
- **7.3.** Additional Representations and Warranties of Forest. Forest hereby represents and warrants to Microbia that, as of the Effective Date:
  - (a) Forest has the sole right, title and interest in and to the Forest Patent Rights listed in Schedule 7.3(a) to this Agreement;
  - (b) Forest is not subject to any agreement with a Third Party that includes a royalty or similar payment obligation to, or other restriction or limitation in favor of, such Third Party (including, for this purpose, to current or former officers, directors, employees, consultants or personnel of Forest or any predecessor) with respect to its rights to practice the Forest Technology;
  - (c) No Forest Patent Rights are subject to, or were developed pursuant to any funding agreement with any government or government agency, except as provided in <u>Schedule 7.3(c)</u> to this Agreement;
  - (d) Forest is not in breach of any material provisions of any agreements with Third Parties relating to the Forest Patent Rights;
  - (e) Forest has no products currently under Development or Commercialization for diagnostic, prophylactic or therapeutic uses in IBS-C, CC or OIC indications, except as provided in <u>Schedule 7.3(e)</u>; and
  - (f) Forest has not received any written or oral claim of ownership, inventorship or patent infringement from any Third Party (including without limitation, by current or former officers, directors, employees, consultants, or

personnel of Forest or any predecessor) with respect to the Forest Technology, and Forest is not aware of any reasonable basis for any such claim.

- 7.4. Representation by Legal Counsel. Each Party hereto represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption shall exist or be implied against the Party which drafted such terms and provisions.
- 7.5. No Inconsistent Agreements. Neither Party has in effect and after the Effective Date neither Party shall enter into any oral or written agreement or arrangement that would be inconsistent with its obligations under this Agreement or limit the ability of either Party to grant the licenses set forth in Section 2 of this Agreement.
- 7.6. Disclaimer. THE FOREGOING WARRANTIES OF EACH PARTY ARE IN LIEU OF ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF NONINFRINGEMENT, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR ANY IMPLIED WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE ALL OF WHICH ARE HEREBY SPECIFICALLY EXCLUDED AND DISCLAIMED. EACH PARTY HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE DEVELOPMENT, MANUFACTURE OR COMMERCIALIZATION OF ANY PRODUCT UNDER THIS AGREEMENT WILL BE SUCCESSFUL.

#### 8. INTELLECTUAL PROPERTY.

**8.1. Disclosure.** During the Term, the Parties shall promptly disclose to one another all Collaboration Know-How (whether patentable or not).

#### 8.2. Ownership.

- 8.2.1. Ownership of Technology. Determinations as to which Party has invented any Patent Right or Know-How shall be made in accordance with the standards of inventorship under U.S. patent law. Subject to the license grants under Section 2 of this Agreement, as between the Parties, Microbia shall own all Microbia Technology and Forest shall own all Forest Technology. Each Party shall own an undivided one-half interest in and to the Joint Technology. In the event inventorship and ownership of any Collaboration Technology cannot be resolved by the Parties with advice of their respective intellectual property counsel, such dispute shall be resolved through arbitration pursuant to Section 12.1.2, provided such arbitration panel shall include at least one arbitrator who is a specialist in U.S. patent law and in chemical and pharmaceutical patents.
- 8.2.2. <u>Employee Assignment</u>. To the extent permissible under Applicable Laws, each Party will cause each employee and contractor conducting work on such Party's behalf under this Agreement to sign a contract that (i) compels prompt disclosure to the Party of all Microbia Technology, Forest Technology, Joint Technology, as applicable, conceived or

reduced to practice by such employee or contractor during any performance under this Agreement, (ii) automatically assigns to the Party all right, title and interest in and to all such Technology and all Patent Rights disclosing or claiming such Technology, and (iii) obligates such persons to similar obligations of confidentiality as set forth in this Agreement. Each Party will require each employee and contractor conducting work on such Party's behalf under this Agreement to maintain records in sufficient detail and in a good scientific manner appropriate for patent purposes to properly reflect all work done.

8.3. Intellectual Property Working Group. The Parties shall promptly establish an intellectual property working group comprised of at least one senior patent attorney from each Party, together with business development personnel and such other representatives of the Parties as the Parties may determine to be appropriate from time to time, to manage and review the patent strategy for inventions made in the course of the Development and to determine patent strategy relating to the Collaboration Patent Rights, to the extent such Collaboration Patent rights are necessary or useful in the Territory to Manufacture, Develop or Commercialize a Collaboration Compound or Product.

## 8.4. Prosecution and Maintenance of Patent Rights.

- 8.4.1. Patent Prosecution and Maintenance. Each of Microbia and Forest will be primarily responsible for the preparation, filing, prosecution and maintenance of the Microbia Patent Rights and the Forest Patent Rights, respectively; provided that, each Party shall provide the other with advance copies of, and a reasonable opportunity to comment upon, proposed patent filings, related prosecution strategies and proposed correspondence with patent officials or other Third Parties relating to any such patents and will consider comments received in good faith and will not unreasonably reject such comments; provided further, that correspondence or other communications or actions which relate to the validity of Collaboration Patent Rights, to the extent such Collaboration Patent Rights are necessary or useful in the Territory to Manufacture, Develop or Commercialize a Collaboration Compound or Product, that are made during the course of an action before a Federal Court, or before the U.S. Patent and Trademark Office in a patent re-examination, re-issuance or interference proceeding shall require the mutual approval of both Parties. A Party providing comments in accordance with this Section shall provide such comments expeditiously and in any event in reasonably sufficient time to meet any filing deadline communicated to it by the other Party. The Party receiving any such patent application and correspondence shall maintain such information in confidence, except for patent applications that have been published and official correspondence that is publicly available.
- 8.4.2. <u>Joint Patent Rights</u>. The intellectual property working group will designate which Party will be responsible for preparing, filing, prosecuting and maintaining Joint Patent Rights. Irrespective of which Party is responsible for filing, prosecuting and maintaining Joint Patent Rights, Forest and Microbia shall equally share the costs for filing, prosecuting and maintaining Joint Patent Rights in the Territory.
- 8.4.3. <u>Reversion Rights.</u> If a Party decides not to file, prosecute or maintain a Patent Right covering, as applicable, Microbia Technology or Forest Technology, to the extent

such Technology is necessary or useful to Manufacture, Develop or Commercialize a Collaboration Compound or Product, with respect to Microbia Technology within the Territory and with respect to Forest Technology whether within or outside of the Territory, it shall give the other Party reasonable notice to that effect sufficiently in advance of any deadline for any filing with respect to such Patent Right to permit the other Party to carry out such activity. After such notice, the other Party may file, prosecute and maintain the Patent Right, and perform such acts as may be reasonably necessary for the other Party to file, prosecute or maintain such Patent Right, at its sole cost and expense. If such other Party does so elect, then the Party which has elected not to pursue such filing, prosecution or maintenance shall provide such cooperation to the other Party, including the execution and filing of appropriate instruments, as may reasonably be requested to facilitate the transition of such patent activities, and shall assign all of its right, title and interest to such patent, other than its rights thereto provided by this Agreement, to the Party electing to pursue such patent activities.

- 8.4.4. Patent Term Extensions. The Parties agree to cooperate in the selection of the appropriate Microbia Patent Rights, Forest Patent Rights or Joint Patent Rights as listed in the patent information section of the Product NDA for filing to obtain a Patent Term Extension pursuant to all applicable laws and regulations ("PTE"), including without limitation supplementary protection certificates and any other extensions that are now or become available in the future wherever applicable to Patent Rights that are applicable to the Product. In addition, the Parties agree to timely compile and file the necessary documentation for a PTE request within sixty days of approval by the FDA of the U.S. NDA for the first indication.
- 8.4.5. <u>Costs and Expenses</u>. Costs and expenses of filing, prosecuting, maintaining, and extending the Collaboration Patent Rights will be included as Development Expense.

#### 8.5. Trademarks.

8.5.1. Product Trademark. Until such time as the Parties determine that the launch by a Third Party of a generic equivalent of the Product is imminent in the Territory (on a country-by-country basis, and based upon objective evidence shared and discussed by both Parties), all Products shall be sold in the Territory under the Trademarks selected by the JCC with advice from the Parties' intellectual property counsel. No such Trademark shall be used outside of the country as to which it has been approved for use by the JCC or outside the Territory, unless otherwise agreed by the Parties in writing. Microbia shall own such Trademarks subject to the license granted to Forest herein, and shall be responsible for the filing, prosecution and maintenance of such Trademarks in the applicable country or countries within the Territory. If Microbia decides not to file, prosecute or maintain a Trademark in a country of the Territory, it shall give Forest reasonable notice to that effect sufficiently in advance of any deadline for any filing with respect to such Trademark in such country to permit Forest to carry out such activity. After such notice, Forest may file, prosecute and maintain such Trademark in such country. The expenses of the selection, filing, prosecution and maintenance of the Trademark shall be included as Commercialization Expense.

- 8.5.2. <u>Trademark Use</u>. The manner of use of the Trademarks shall be subject to periodic review by the JCC. Neither Party shall use the Trademarks in a way that is inconsistent with the usage instructions approved by the JCC, and neither Party shall use a trademark confusingly similar to one of the Trademarks with any of its other products or, except as otherwise provided herein, use the Trademarks in combination with its other trademarks in a manner which would create combination marks. The Parties shall utilize the Trademarks within the Territory only in accordance with this Agreement.
- 8.5.3. Party Name on Product Promotional Material. Subject to Applicable Laws, all Product promotional material in the U.S. will include Microbia's trade name, trademark, and other logos requested by Microbia (the "Microbia House Marks") in a manner that has equal prominence with Forest's marks. To effectuate the purposes of this Agreement, Microbia hereby grants to Forest a royalty free license (with right of sublicense to its Affiliates or as expressly provided in Section 2.6), to use and display the Trademarks, and the Microbia House Marks in connection with the Commercialization of a Product in the Field, with respect to the Trademarks in the Territory, and with respect to the Microbia House Marks in the U.S., and all in accordance with this Agreement. All goodwill arising from the use of such Trademarks and Microbia House Marks shall inure to the benefit of Microbia.

## 8.6. Enforcement of Technology Rights.

- 8.6.1. Notice. If Microbia or Forest becomes aware that any Microbia Technology, Forest Technology, in each such case, which Technology is necessary or useful in the Territory to Manufacture, Develop or Commercialize a Collaboration Compound or Product, or Joint Technology is infringed or misappropriated by a Third Party in the Territory in the Field or is subject to a declaratory judgment action arising from such infringement (collectively, an "Infringement"), Microbia or Forest, as the case may be, shall promptly notify the other Party.
- 8.6.2. Enforcement. The Party that owns the Technology which is the subject of the Infringement shall have the first right (but not the obligation), to enforce such Technology against such Infringement, provided that in the event Technology owned by both Parties is the subject of the Infringement, the Parties shall cooperate and act in concert to enforce their Technology against such Infringement; provided, further, that (i) Forest shall have the first right to bring and control any action or proceeding in connection with an ANDA filed by a Third Party with respect to a Product, as further provided in Section 8.10 below (an "ANDA Proceeding") related to Microbia Technology, Forest Technology or Joint Technology in the Territory or any other proceeding to enforce any of such intellectual property rights against distributors or proposed distributors of generic equivalents or counterfeits of the Product in the Territory, (ii) the other Party shall have the right to join such proceeding at any time at its own expense and shall do so at any time (subject to Section 8.6.3) if it is deemed to be a necessary Party by the tribunal in which the Infringement is being prosecuted, and (iii) neither Party shall admit the invalidity or unenforceability of any Collaboration Technology which Collaboration Technology is necessary or useful in the Territory to Manufacture, Develop or Commercialize a Collaboration Compound or Product or other Technology owned solely by or jointly with the other Party without the other Party's prior

written consent. In the event the Party with the first right to control an action or proceeding pursuant to this Section declines to prosecute the infringing technology or to defend such claim within ninety (90) days (or such shorter period as may be required to comply with legal or regulatory deadlines which relate to such infringement, including, without limitation, in connection with ANDA Proceedings) of becoming aware thereof, the other Party shall have the right to so enforce or defend. Irrespective of which Party controls an action pursuant to this Section, the Parties will collaborate in the choice of counsel with respect to such action and the comments of the other Party shall not be unreasonably rejected with respect to strategic decisions and their implementation with respect to such action. In furtherance of the foregoing, the Party responsible for any such action shall keep the other Party reasonably informed, in person or by telephone, regarding the status and costs of such action or proceeding prior to and during any such enforcement. Neither Party shall settle any such action without the written consent of the other Party, such consent not to be unreasonably withheld. Neither Party shall incur any liability to the other as a consequence of such litigation or any unfavorable decision resulting therefrom, including any decision holding any of the Microbia Technology, Forest Technology, or Joint Technology invalid, not infringed, not misappropriated or unenforceable.

8.6.3. <u>Costs and Recoveries</u>. The Parties agree that, irrespective of which Party prosecutes the action, the costs of such prosecution or defense of validity, and the proceeds of any awards, judgments or settlements obtained in connection with an Infringement in the Territory shall be [shared equally by the Parties].

#### 8.7. Third Party Claims.

- 8.7.1. Third Party Claims Course of Action. If the Development, Commercialization or Manufacture of a Product under this Agreement is alleged by a Third Party to infringe a Third Party's patent right(s) or misappropriate a Third Party's trade secret, the Party becoming aware of such allegation shall promptly notify the other Party thereof, in writing, reasonably detailing the claim.
- 8.7.2. Third Party Suit. If a Third Party sues a Party (the "Sued Party") alleging that the Sued Party's or the Sued Party's Sublicensees', Development, Manufacture or Commercialization of any Collaboration Compound of the Product infringes or shall infringe said Third Party's patent right(s) or misappropriates said Third Party's trade secret, then upon the Sued Party's request and in connection with the Sued Party's defense of any such Third Party suit, the other Party shall provide reasonable assistance to the Sued Party for such defense and shall join such suit if deemed a necessary party. The Sued Party shall keep the other Party, if such other Party has not joined in such suit, reasonably informed on a quarterly basis, in person or by telephone, prior to and during the pendency of any such suit. The Sued Party shall not admit the invalidity of any patent within the Microbia Patent Rights, the Forest Patent Rights or the Joint Patent Rights, nor settle any such suit, without written consent of the other Party, such consent not to be unreasonably withheld. Subject to the Parties' respective indemnity obligations pursuant to Section 11.2 and 11.3, all litigation expenses, including settlement costs, royalties paid in settlement of any such suit, and the payment of any damages to the Third Party, [will be treated as Development Expenses or, as applicable,

Commercialization Expenses and will be shared equally by the Parties in accordance with Section 5.4.1].

- 8.8. Third Party Licenses. Subject to Section 8.7.2, the Parties, on the recommendation of their respective intellectual property counsel and members of their business development groups shall determine whether it is advisable at any time to obtain a license to any intellectual property owned or controlled by a Third Party, and if so, on what terms (economic or otherwise), and by which Party. Any such license agreement shall be on terms mutually agreed by the Parties. For all Third Party Patent Rights licensed pursuant to this Section 8.8, all license fees, royalties, and milestone payments paid to the Third Party [will be treated as Development Expenses or, as applicable, Commercialization Expenses and shared equally by the Parties in accordance with Section 5.4.1].
- **8.9. Patent Marking**. Each Party agrees to mark and have its Affiliates and all Sublicensees mark all Products (or their containers or labels) sold pursuant to this Agreement in accordance with the applicable statutes or regulations in the country or countries of manufacture and sale thereof.
- 8.10. Patent Certifications. Each Party shall immediately give written notice to the other of any certification of which it becomes aware has been filed pursuant to 21 U.S.C. § 355(b)(2)(A), or § 355(j)(2)(A)(vii) (or any amendment or successor statute thereto) claiming that the Microbia Patent Rights, Forest Patent Rights, or Collaboration Patent Rights covering the Product are invalid or that infringement shall not arise from the manufacture, use or sale of such Third Party product by a Third Party. Forest shall have the right, in the first instance, to commence an ANDA Proceeding in connection with any such certification. If Forest decides not to bring infringement proceedings against the Third Party making such a certification with respect to any Product, Forest will give notice to Microbia of its decision not to bring suit within ten (10) business days after receipt of notice of such certification (or, if the time period permitted by law is less than twenty (20) business days, within half of the time period permitted by law for Forest to commence such action) and Microbia may then, but shall not be obligated to, bring suit against the Third Party that filed the certification. Any suit by either Party may be in the name of either or both Parties, as may be required by law. For this purpose, the Party not bringing suit will execute such legal papers necessary for the prosecution of such suit as may be reasonably requested by the Party bringing suit.
- **8.11.** No Implied Licenses. Except as expressly set forth in this Agreement, no right or license under any Microbia Technology or Forest Technology is granted or shall be granted by implication as a result of the respective rights of the Parties under this Agreement. All such rights or licenses are or shall be granted only as expressly provided in this Agreement.
- **8.12. Privileged Communications.** In furtherance of this Agreement, it is expected that Forest and Microbia will, from time to time, disclose to one another privileged communications with counsel, including opinions, memoranda, letters and other written, electronic and verbal communications. Such disclosures are made with the understanding that they shall remain confidential, they will not be deemed to waive any applicable attorney-client privilege and that they are made in connection with the shared community of legal interests

existing between Microbia and Forest, including the community of legal interests in avoiding infringement of any valid, enforceable patents of Third Parties and maintaining the validity of Microbia Patent Rights, Forest Patent Rights and Joint Patent Rights.

#### 9. INTENTIONALLY OMITTED.

#### 10. TERM AND TERMINATION.

**10.1. Term.** The term of this Agreement shall commence on the Effective Date and, unless earlier terminated as provided in this Section 10 shall continue in full force and effect on a country-by-country basis as long as any Product is being Developed or Commercialized for use in the Field (the "<u>Term</u>").

#### 10.2. Termination for Cause.

10.2.1. Termination for Material Breach. This Agreement may be terminated effective immediately on a country-by-country basis by written notice by either Party at any time during the Term if the other Party materially breaches this Agreement, which breach remains uncured for [sixty (60)] days measured from the date written notice of such breach is given to the breaching Party, which notice shall specify the nature of the breach and demand its cure, provided, however, that if such breach is not capable of being cured within the stated period and the breaching Party uses Commercially Reasonable Efforts to cure such breach during such period and presents a mutually agreeable remediation plan for such breach, this Agreement shall not terminate and the cure period shall be extended for such period provided in the remediation plan as long as the breaching party continues to use Commercially Reasonable Efforts to pursue the cure as provided in such remediation plan. In the event the Parties dispute in good faith the existence of a material breach or a Party's diligence in attempting to cure a material breach, termination of this Agreement shall not be deemed to occur unless and until such dispute has been referred for resolution in accordance with Section 12.1.2 hereof, material breach of the Agreement or failure to make diligent efforts to cure such breach has been established by an arbitration thereunder and, if such breach can be cured by the payment of money or the taking of specific remedial actions, the breaching party does not pay the amount so determined to be due within [ten (10)] days of receipt of the arbitration decision or otherwise diligently undertake and complete such remedial actions within the timeframe established by such arbitration decision. In the event a material breach affects only certain but not all countries in the Territory, the remedy of termination shall only be effective, on a country-by-country basis with respect to the countries as to which such material breach occurred. In the case of any uncured material breach by Microbia, in lieu of termination of this Agreement, Forest may terminate Microbia's Operational Rights hereunder. Notwithstanding anything to the contrary set forth herein but subject to the limitations set forth in Section 11.6, termination shall not be deemed to relieve a defaulting party from any liability arising from such default.

10.2.2. <u>Forest Right of Termination</u>. Prior to its expiration, this Agreement may be terminated in its entirety at any time by Forest effective upon at least [<u>one hundred and eighty (180)</u>] days prior written notice to Microbia for any reason. If Forest terminates for a

material safety issue, Forest will provide all assistance reasonably requested by Microbia for at least [one hundred and eighty (180)] days after such termination to identify, further characterize and fully document such safety issue and, subject to the last sentence of this Section 10.2.2, provide such other assistance as might be reasonably useful or necessary for Microbia to continue with the development or commercialization of the Colloboration Compounds or Product, but shall not be required to undertake any studies or other Development not then provided by the Development Plan. In addition, Forest shall not be required to undertake any Development, Manufacturing or Commercialization activities or any other activities, in each case which implicate a material safety issue during such [one hundred and eighty (180)] day period.

- 10.2.3. <u>Violation of Law</u>. This Agreement may be terminated by either Party on giving thirty (30) days' written notice to the other, which shall be effective on the expiration date of such thirty (30) day period in the event that the other Party (the "<u>Violating Party</u>") is convicted of a felony for violating, or a final, non-appealable order is issued by a court of competent jurisdiction finding that the Violating Party violated, any Applicable Laws, the Federal Foreign Corrupt Practices Act or any securities laws or regulations (collectively, the "<u>Relevant Laws</u>"), which are of such a nature that the Violating Party's violation of such Relevant Laws would prevent or substantially diminish a Party from performing or having the ability to perform its obligation pursuant to this Agreement, except, however, this clause shall have no application in the case of civil or criminal proceedings that either Party has disclosed to the other Party in writing prior to the Effective Date or that are otherwise disclosed in either Party's reports or statements filed pursuant to the Securities Exchange Act of 1934 prior to the Effective Date. Such notice of termination must be given within thirty (30) days of the terminating Party becoming aware of the circumstances described in this Section 10.2.3.
- 10.2.4. Effects of Termination by Forest without Cause or by Microbia with Cause. If this Agreement is terminated by Forest pursuant to Section 10.2.2, or by Microbia pursuant to Sections 10.2.1, 10.2.3 or 10.2.6:
  - (a) All licenses granted by Microbia to Forest hereunder shall automatically terminate;
  - (b) All licenses granted by Forest to Microbia shall become fully paid up, irrevocable, perpetual, royalty-free licenses;
  - (c) Forest shall assign to Microbia all right, title and interest in and to: (i) all Regulatory Submissions and Regulatory Approvals pertaining to any Collaboration Compound or Product Controlled by Forest, (ii) all of Forest's interest in any Trademark (including, without limitation, the goodwill symbolized by such Trademark) used to brand the Product, and (iii) all of Forest's interest in any copyrights to the extent necessary or useful for Commercializing the Product;
  - (d) Forest shall grant, and hereby grants, to Microbia a worldwide, exclusive (even as to Forest), royalty-free and fully sublicensable license to practice any invention claimed in the Forest Patent Rights or Joint Patent Rights,

and to practice the Forest Know-How and Joint Know-How for purposes of Development and Commercialization of the Collaboration Compound or the Product in the Field; and

- (e) Forest shall furnish Microbia with reasonable cooperation to assure a smooth transition of any clinical or other studies in progress related to a Collaboration Compound or Product which Microbia determines to continue in compliance with Applicable Laws and ethical guidelines applicable to the transfer or termination of any such studies. In the event that Microbia informs Forest that it does not intend to continue specific development activities then in progress, costs incurred in closing out such activities shall be allocated in accordance with the allocation of the applicable Development Expense responsibilities provided hereunder. In addition, Forest will return all Microbia Confidential Information to Microbia. Except as provided by this Section, Forest shall have no further obligation to Microbia in respect of the termination of this Agreement pursuant to this Section, including, without limitation, the payment of any Development Milestones or Sales Milestones, the obligation of payment of which has accrued following the furnishing by Forest of notice of termination.
- (f) Microbia will have the immediate right to terminate Forest's Operational Rights except that Forest will continue to provide Detailing in accordance with its obligations hereunder until the effective date of termination.
- (g) Until termination is effective, Forest shall continue to perform its obligations under the Development Plan and Commercialization Plan then in effect and pay all costs allocated for it to pay in accordance with any budgets then in effect, except with respect to activities that Microbia elects to discontinue.
- (h) Forest will make the payment referred to under Section 5.1(ii) if unpaid as of the effective date of termination.

Subsection (a) above will be effective upon any such termination, and subsections (b), (c), (d), (e) and (f) above shall be effective upon termination, or if such termination is by Forest pursuant to Section 10.2.2, upon the earlier of such termination or Microbia's earlier election.

- 10.2.5. Effects of Termination by Forest. If Forest is entitled to terminate this Agreement pursuant to Section 10.2.1, Section 10.2.3 or Section 10.2.6, Forest may elect to either terminate the agreement (in which case all licenses granted by either Party to the other shall terminate and neither Party shall have any further liability to the other except to the extent of provisions which survive the termination of this Agreement by their respective terms and obligations accrued but remaining outstanding as of the effectiveness of termination) or elect to continue the Agreement, subject to the following provisions which shall be effective upon Forest's notice of such election:
  - (a) Microbia's Operational Rights shall terminate; provided that in any event Forest will continue to periodically provide information to Microbia

with respect to manufacturing, development and commercialization matters to the extent reasonably related to Microbia's continuing rights under the Agreement.

- (b) The license granted by Forest to Microbia pursuant to Section 2.3(ii) shall terminate with respect to any Forest Technology developed or acquired from and after the exercise by Forest of its rights pursuant to this Section.
- (c) Microbia shall furnish Forest with reasonable cooperation to assure a smooth transition of any Development or Commercialization activities then being conducted or performed by Microbia which Forest determines to continue in compliance with Applicable Laws and ethical guidelines applicable to the transfer or termination of any such activities. In the event Forest informs Microbia that it does not intend to continue specific Development or Commercialization activities then in progress, costs incurred in closing out such activities shall be allocated in accordance with the allocation of the applicable Development Expense or Commercialization Expense responsibilities provided hereunder. Except to the extent provided in this Section, the Agreement shall remain in full force and effect (*i.e.*, Forest and Microbia shall continue to share Net Profits and Net Losses as provided herein).
- (d) Forest will make the payment referred to under Section 5.1(ii) if unpaid as of the effective date of termination.
- 10.2.6. <u>Effects of termination for Change of Control</u>. If this Agreement is terminated by either Party pursuant to Section 10.3.2:
  - (a) All licenses granted by the terminating Party to the Target Party hereunder shall automatically terminate;
  - (b) All licenses granted by the Target Party to the terminating Party shall become fully paid up, irrevocable, perpetual, royalty-free licenses;
  - (c) The Target Party shall assign to the terminating Party all right, title and interest in and to: (i) all Regulatory Submissions and Regulatory Approvals pertaining to any Collaboration Compound or Product Controlled by the Target Party, (ii) all of the Target Party's interest in any Trademark (including, without limitation, the goodwill symbolized by such Trademark) used to brand the Product, and (iii) all of the Target Party's interest in any copyrights to the extent necessary or useful for Commercializing the Product;
  - (d) The Target Party shall grant, and hereby grants, to the terminating Party a worldwide, exclusive (even as to the Target Party), royalty-free and fully sublicensable license (i) to practice any invention claimed in the Joint Patent Rights and to practice the Joint Know-How, (ii) to practice, in the case of termination by Microbia, any invention claimed in the Forest Patent

Rights and to practice the Forest Know-How, and (iii) to practice, in the case of termination by Forest, any inventions claimed in the Microbia Patent Rights and to practice the Microbia Know-How, in each case to develop, manufacture and commercialize the Collaboration Compound and the Product in the Field and, in the case of termination by Forest, in the Territory and, in the case of termination by Microbia, in any territory;

- The Target Party shall furnish the terminating Party with reasonable cooperation to assure a smooth transition of any clinical or other studies in progress related to a Collaboration Compound or Product which the terminating Party determines to continue in compliance with Applicable Laws and ethical guidelines applicable to the transfer or termination of any such studies. In the event that the terminating Party informs the Target Party that it does not intend to continue specific development activities then in progress, costs incurred in closing out such activities shall be allocated in accordance with the allocation of the applicable Development Expense responsibilities provided hereunder. In addition, the Target Party will return all the terminating Party Confidential Information to the terminating Party. Except as provided by this Section, the Target Party shall have no further obligation to the terminating Party in respect of the termination of this Agreement pursuant to this Section, including, without limitation, the payment of any Development Milestones or Sales Milestones, the obligation of payment of which has accrued following the furnishing by the Target Party of notice of termination;
- (f) The terminating Party will have the immediate right to terminate the Target Party's Operational Rights except that the Target Party will continue to provide Detailing in accordance with its obligations hereunder until the effective date of termination; and
- (g) Until termination is effective, the Target Party shall continue to perform its obligations under the Development Plan and Commercialization Plan then in effect and pay all costs allocated for it to pay in accordance with any budgets then in effect, except with respect to activities that the terminating Party elects to discontinue.
- (h) In the case of termination by either Party, Forest will make the payment referred to under Section 5.1(ii) if unpaid as of the effective date of termination.

Subsection (a) above will be effective upon any such termination, and subsections (b), (c), (d), (e) and (f) above shall be effective upon such termination or the terminating Party's earlier election.

10.2.7. <u>Bankruptcy</u>. This Agreement may be terminated by written notice by either Party at any time during the term of this Agreement 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.

#### 10.3. Change of Control.

10.3.1. <u>Change of Control Notice</u>. Each Party shall notify the other Party in writing, referencing this Section of the Agreement, immediately upon any Change of Control, and shall provide such notice where possible at least sixty (60) days prior to the Change of Control.

## 10.3.2. Consequences of a Change of Control.

- (a) In the event that a Party is subject to a Change of Control which was approved or recommended by the Board of Directors of such Party as constituted immediately prior to such Change of Control and which does not involve an Impairment (as defined below), but in connection therewith senior management of the U.S. pharmaceutical operations of the entity resulting from such Change of Control does not substantially comprise such management as constituted prior to such Change of Control, then this Agreement shall continue in effect in accordance with its terms, except that, in the event of a Change of Control of Forest, consensus of the Parties would be required for all decisions relating to Commercialization pursuant to the provisions of Section 3.6.
- In the event that a Party (the "Target Party") is subject to a Change of Control which was not approved or recommended by the Board of Directors of the Target Party as constituted immediately prior to such Change of Control, or if so approved or recommended, could reasonably be expected to lead to an Impairment (as defined below), the Target Party will notify the other Party at least [thirty (30)] days prior to the closing of such transaction, and such other Party may elect, in its sole discretion, to (i) continue the Agreement in accordance with its terms, (ii) terminate the Agreement on [twelve] months notice, during which period the Agreement would continue in effect in accordance with its terms, except that consensus would be required for all decisions relating to Commercialization pursuant to the provisions of Section 3.6, or (iii) terminate the Agreement effective upon [ninety (90)] days written notice of termination, in each of cases (ii) and (iii) such notice to be delivered within [sixty (60)] days after the Fair Market Value is determined pursuant to this Section (b). Within [thirty (30)] days following a Party's receipt of notice from the Target Party of a Change of Control, such Party shall provide notice to the Target Party requesting a determination of the Fair Market Value of the Product rights subject to acquisition by such Party upon a termination pursuant to this Section, and the failure to so

request such valuation shall be deemed the election to continue the Agreement in accordance with its terms. Such determination shall be made by the Parties in good faith, and if such determination is not made within [90 days] of the request, then as determined by a Valuation Panel. Upon any termination of this Agreement pursuant to this Section, the terminating Party shall be entitled to receive the assignments and transitional activities described in Section 10.2.6. In connection with such termination, the terminating Party shall be required to pay the Target Party an amount equal to the Fair Market Value of the Product rights reacquired by the terminating Party in a lump sum payment within [sixty (60)] days of the effective date of the termination.

- deemed to occur if (a) it is reasonably anticipated that the entity resulting from such Change of Control will be unable to perform its obligations in accordance with the terms of the Agreement, as reasonably determined based on objective criteria available to both Parties, including without limitation, the new entity's financial position and product pipeline, (b) the product line of the entity which results from the Change of Control includes a product, whether or not a Covered Product, which is indicated for the treatment of IBS-C, CC, OIC (unless as to any such indication, the JDC has determined not to pursue Development for such indication) or any other indication for which the Product is then being Commercialized in the Territory pursuant to this Agreement, and such resulting entity does not comply with the divestiture provisions of Section 6.2.2 or, if such Change of Control occurs after the Restricted Period, the applicable provisions of Section 6.2.1. For purposes of such compliance, the date of the Change of Control shall be deemed the date of the "Covered Product Transaction."
- 10.4. Survival of Certain Obligations. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing before such expiration or termination. The provisions of this Agreement that must, by their nature, survive expiration or termination of this Agreement to give effect to their intent, shall so survive, including without limitation Section 2.5; Section 2.7; Section 5.4.5; Section 6; Section 10 and Section 11. Any expiration or early termination of this Agreement shall be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement before termination.

#### 11. PRODUCT LIABILITY, INDEMNIFICATION AND INSURANCE.

11.1. Sharing of Liability Expenses. Except where caused by the gross negligence or willful misconduct of a Party seeking reimbursement, the Parties shall share equally all losses, damages, liabilities, settlements, penalties, fines and expenses (including, without limitation, reasonable attorneys' fees and expenses) (collectively, "Liability") arising out of or caused by (a) the Manufacture, Development or Commercialization of the Product; (b) the death or bodily injury of any person on account of the use of the Product; and/or (c) any recall or withdrawal of the Product (collectively, "Shared Liability Claims"), other than to the extent the responsibility for any such Liabilities is covered by the indemnification provisions of Sections 11.2 or 11.3.

- 11.2. Indemnification by Microbia. Microbia shall indemnify, defend and hold harmless Forest, its Affiliates, and each of its and their respective employees, officers, directors agents and permitted Sublicensees (each, an "Forest Indemnified Party") from and against any and all Liabilities that the Forest Indemnified Party may be required to pay to one or more Third Parties to the extent resulting from or arising out of:
  - (a) any Microbia representation or warranty set forth herein being untrue in any material respect when made or any material breach by Microbia of any of its covenants or obligations hereunder; or
  - (b) any Shared Liability Claims relating to the Product caused by the gross negligence or willful misconduct of Microbia;

except in each case, to the extent caused by the gross negligence or willful misconduct of Forest or any Forest Indemnified Party, or by breach of this Agreement by Forest.

- 11.3. Indemnification by Forest. Forest shall indemnify, defend and hold harmless Microbia, its Affiliates, Sublicensees, distributors and each of its and their respective employees, officers, directors and agents (each, a "Microbia Indemnified Party") from and against any and all Liabilities that the Microbia Indemnified Party may be required to pay to one or more Third Parties to the extent resulting from or arising out of:
  - (a) any Forest representation or warranty set forth herein being untrue in any material respect when made or a material breach by Forest of any of its covenants or obligations hereunder; or
  - (b) any Shared Liability Claims relating to a Product caused by the gross negligence or willful misconduct of Forest; or
  - (c) any claims arising from or related to Forest's Commercialization activities in the Royalty Territory;

except in each case, to the extent caused by the gross negligence or willful misconduct of Microbia or any Microbia Indemnified Party, or by breach of this Agreement by Microbia.

11.4. Procedure. Each Party shall notify the other in the event it becomes aware of a claim for which indemnification may be sought hereunder or for which Liability is shared pursuant to this Section 11. In case any proceeding (including any governmental investigation) shall be instituted involving any Party in respect of which indemnity may be sought pursuant to this Section 11, such Party (the "Indemnified Party") shall promptly notify the other Party (the "Indemnifying Party") in writing and the Indemnifying Party and Indemnified Party shall meet to discuss how to respond to any claims that are the subject matter of such proceeding. The Indemnifying Party, upon request of the Indemnified Party, shall retain counsel reasonably satisfactory to the Indemnified Party to represent the Indemnified Party and shall pay the fees and expenses of such counsel related to such proceeding. In any such proceeding, the

Indemnified Party shall have the right to retain its own counsel, but the fees and expenses of such counsel shall be at the expense of the Indemnified Party unless (i) the Indemnifying Party and the Indemnified Party shall have mutually agreed to the retention of such counsel or (ii) the named parties to any such proceeding (including any impleaded parties) include both the Indemnifying Party and the Indemnified Party and representation of both Parties by the same counsel would be inappropriate due to actual or potential differing interests between them. All such fees and expenses incurred pursuant to Section 11.2 or 11.3 shall be reimbursed as they are incurred, and all such fees and expenses incurred pursuant to Section 11.1 shall be reimbursed in accordance with Section 5.4. The Indemnifying Party shall not be liable for any settlement of any proceeding unless effected with its written consent. The Indemnifying Party shall not, without the written consent of the Indemnified Party, effect any settlement of any pending or threatened proceeding in respect of which the Indemnified Party is, or arising out of the same set of facts could have been, a party and indemnity could have been sought hereunder by the Indemnified Party, unless such settlement includes an unconditional release of the Indemnified Party from all liability on claims to which the indemnity relates that are the subject matter of such proceeding.

- 11.5. Insurance. Each Party further agrees to use its reasonable efforts to obtain and maintain, during the term of this Agreement, Commercial General Liability Insurance, including Products Liability Insurance, with reputable and financially secure insurance carriers to cover its indemnification obligations under Sections 11.2 or 11.3, as applicable, or self-insurance, with limits of not less than \$[5] million per occurrence and \$[10] million in the aggregate (\$[50] million in the aggregate from and after Commercial Launch).
- 11.6. Liability Limitations. NOTWITHSTANDING THE FOREGOING, IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES UNDER ANY COLLABORATION AGREEMENT, EXCEPT TO THE EXTENT THE DAMAGES RESULT FROM A PARTY'S WILLFUL MISCONDUCT OR ARISE FROM A PARTY'S INDEMNIFICATION OBLIGATIONS UNDER THIS SECTION 11.

#### 12. MISCELLANEOUS.

#### 12.1. Governing Law, Jurisdiction; Dispute Resolution.

12.1.1. <u>Governing Law</u>. The interpretation and construction of this Agreement shall be governed by the laws of the State of New York, 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.

#### 12.1.2. Arbitration.

(a) <u>Claims</u>. Any claim, dispute, or controversy of whatever nature arising between the Parties out of or relating to this Agreement that is not resolved under Section 12.1.3 within the required thirty (30) day time period, including without limitation, any action or claim based on tort, contract, or statute

(including any claims of breach or violation of statutory or common law protections from discrimination, harassment and hostile working environment), or concerning the interpretation, effect, termination, validity, performance and/or breach of this Agreement ("Claim"), shall be resolved by final and binding arbitration before a panel of three experts with relevant industry experience (the "Arbitrators"). One Arbitrator shall be chosen by Microbia and one Arbitrator shall be chosen by Forest within fifteen (15) days from the notice of initiation of arbitration. The third Arbitrator shall be chosen by mutual agreement of the Arbitrator chosen by Microbia and the Arbitrator chosen by Forest within fifteen (15) days of the date that the last of such Arbitrators were appointed. The Arbitrators shall be administered by the International Chamber of Commerce (the "Administrator") in accordance with its then existing arbitration rules or procedures regarding commercial or business disputes. The arbitration shall be held in Boston, Massachusetts if requested by Forest and in New York, New York if requested by Microbia. The arbitrators shall be instructed by the Parties to complete the arbitration within ninety (90) days after selection of the final Arbitrator.

- (b) Arbitrators' Award. The Arbitrators shall, within fifteen (15) calendar days after the conclusion of the arbitration hearing, issue a written award and statement of decision describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The decision or award rendered by the Arbitrators shall be final and non-appealable, and judgment may be entered upon it in accordance with applicable law in the State of New York or Massachusetts, as applicable, or any other court of competent jurisdiction. The Arbitrators shall be authorized to award compensatory damages, but shall NOT be authorized (i) to award non-economic damages, such as for emotional distress, pain and suffering or loss of consortium, (ii) to award punitive damages, or (iii) to reform, modify or materially change this Agreement or any other agreements contemplated hereunder; provided, however, that the damage limitations described in parts (i) and (ii) of this sentence will not apply if such damages are statutorily imposed.
- (c) <u>Costs</u>. Each Party shall bear its own attorney's fees, costs, and disbursements arising out of the arbitration and the costs of the arbitrator selected by it, and shall pay an equal share of the fees and costs of the third arbitrator; provided, however, the Arbitrators shall be authorized to determine whether a party is the prevailing party, and if so, to award to that prevailing party reimbursement for its reasonable attorneys' fees, costs and disbursements (including, for example, expert witness fees and expenses, photocopy charges, travel expenses, etc.), and/or the fees and costs of the Administrator and the Arbitrators.
- (d) <u>Compliance with this Agreement</u>. Unless the Parties otherwise agree in writing, during the period of time that any arbitration proceeding is

pending under this Agreement, the Parties shall continue to comply with all those terms and provisions of this Agreement that are not the subject of the pending arbitration proceeding.

- (e) <u>Injunctive or Other Equity Relief</u>. Nothing contained in this Agreement shall deny any Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing arbitration proceeding.
- 12.1.3. <u>Dispute Resolution</u>. In the event of a dispute arising out of or relating to this Agreement either Party shall provide written notice of the dispute to the other, in which event the dispute shall be referred to the executive officers designated below or their successors, for attempted resolution by good faith negotiations within thirty (30) days after such notice is received. Said designated officers are initially as follows:

For Microbia: its Chief Executive Officer or his designate For Forest: its Chief Executive Officer or his designate

In the event the designated executive officers do not resolve such dispute within the allotted thirty (30) days, either Party may, after the expiration of the thirty (30) day period, seek to resolve the dispute through arbitration in accordance with this Section 12.1.2. Notwithstanding the preceding, the Parties acknowledge that the failure of the JCC or JDC to reach consensus as to any matter, which failure does not involve a breach by a Party of its obligations hereunder, shall not be deemed a dispute which may be referred for resolution by arbitration hereunder.

12.2. Force Majeure. No liability shall result from, and no right to terminate shall arise, in whole or in part, based upon any delay in performance or non-performance, in whole or in part, by either of the Parties to this Agreement to the extent that such delay or nonperformance is caused by an event of Force Majeure. "Force Majeure" means an event that is beyond a non-performing Party's reasonable control, including an act of God, act of the other Party, strike, lock-out or other industrial/labor dispute, war, riot, civil commotion, terrorist act, malicious damage, epidemic, quarantine, fire, flood, storm, natural disaster or compliance with any law or governmental order, rule, regulation or direction, whether or not it is later held to be invalid or inapplicable. The Force Majeure Party shall within ten (10) days of the occurrence of the Force Majeure event, give written notice to the other Party stating the nature of the Force Majeure event, its anticipated duration and any action being taken to avoid or minimize its effect. Any suspension of performance shall be of no greater scope and of no longer duration than is reasonably required and the Force Majeure Party shall use reasonable effort to remedy its inability to perform; provided, however, if the suspension of performance continues or is anticipated to continue for thirty (30) days after the date of the occurrence, the unaffected Party shall have the right but not the obligation to perform on behalf of the Force Majeure Party for a period of such Force Majeure and such additional period as may be reasonably required to assure a smooth and uninterrupted transition of such activities. If such failure to perform would constitute a material breach of this Agreement in the absence of such event of Force Majeure, and continues for one (1) year from the date of the occurrence and the Parties are not able to

agree on appropriate amendments within such period, such other Party shall have the right, notwithstanding the first sentence of this Section 12.2, to terminate this Agreement (including the right to elect to terminate the other Party's Operational Rights under this Agreement in lieu of termination, as provided by and subject to the provisions of Section 10.2.4 and 10.2.5) immediately by written notice to the Force Majeure Party, in which case neither Party shall have any liability to the other except for those rights and liabilities that accrued prior to the date of termination and the consequences of termination pursuant to Sections 10.2.4 or 10.2.5, as applicable, as if such termination was a termination as to which such consequences applied.

- 12.3. Additional Approvals. Forest and Microbia shall cooperate and use respectively all reasonable efforts to make all other registrations, filings and applications, to give all notices and to obtain as soon as practicable all governmental or other consents, transfers, approvals, orders, qualifications authorizations, permits and waivers, if any, and to do all other things necessary or desirable for the consummation of the transactions as contemplated hereby. Neither Party shall be required, however, to divest or out-license products or assets or materially change its business if doing so is a condition of obtaining any governmental approvals of the transactions contemplated by this Agreement.
- 12.4. Waiver and Non-Exclusion of Remedies. Party's failure to enforce, at any time or for any period of time, any provision of this Agreement, or to exercise any right or remedy shall not constitute a waiver of that provision, right or remedy or prevent such Party from enforcing any or all provisions of this Agreement and exercising any rights or remedies. To be effective any waiver must be in writing. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by law or otherwise available except as expressly set forth herein.

#### 12.5. Notices.

12.5.1. Notice Requirements. Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if delivered by hand or sent by facsimile transmission (with transmission confirmed) or by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in Section 12.5.2 or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 12.5.1. Such Notice shall be deemed to have been given as of the date delivered by hand or transmitted by facsimile (with transmission confirmed) or on the second Business Day (at the place of delivery) after deposit with an internationally recognized overnight delivery service. This Section is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

#### 12.5.2. Address for Notice.

For: Microbia, Inc. 320 Bent Street

Cambridge, MA 02141 Fax: 617-494-0908

Attn: Vice President, Business Development

#### With a copy to:

Ropes & Gray LLP One International Place Boston, MA 02110 Fax: 617-951-7050 Attn: Marc Rubenstein

For: Forest Laboratories, Inc.

909 Third Avenue New York, NY 10022 Fax: 212-224-6740

Attn: Chief Executive Officer

#### With a copy to:

Forest Laboratories, Inc. 909 Third Avenue
New York, NY 10022
Fax: 212-224-6740
Attn: General Counsel

- 12.6. Entire Agreement. This Agreement, constitutes the entire agreement between the Parties with respect to the subject matter of the Agreement. This Agreement supersedes all prior agreements, whether written or oral, with respect to the subject matter hereof. Each Party confirms that it is not relying on any representations, warranties or covenants of the other Party except as specifically set out in this Agreement. Nothing in this Agreement is intended to limit or exclude any liability for fraud. All Schedules or Exhibits referred to in this Agreement are intended to be and are hereby specifically incorporated into and made a part of this Agreement. In the event of any inconsistency between any such Schedules or Exhibits and this Agreement, the terms of this Agreement shall govern.
- **12.7. Amendment.** Any amendment or modification of this Agreement must be in writing and signed by authorized representatives of both Parties.
- 12.8. Assignment. Neither Party may assign its rights or delegate its obligations under this Agreement, in whole or in part without the prior written consent of the other Party, except that each Party shall always have the right, without such consent, (a) to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any of its Affiliates, and (b) on written notice to the other Party, assign any or all of its rights and delegate or subcontract any or all of its obligations hereunder to any of its Affiliates. Notwithstanding the foregoing, each Party shall remain responsible for any failure to perform on the part of any

such Affiliates. Any attempted assignment or delegation in violation of this Section shall be void.

- **12.9. No Benefit to Others.** The provisions of this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they shall not be construed as conferring any rights in any other persons except as otherwise expressly provided in this Agreement.
- **12.10. Counterparts.** This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which taken together shall be deemed to constitute one and the same instrument. An executed signature page of this Agreement delivered by facsimile transmission shall be as effective as an original executed signature page.
- 12.11. Severability. To the fullest extent permitted by applicable law, the Parties waive any provision of law that would render any provision in this Agreement invalid, illegal or unenforceable in any respect. If any provision of this Agreement is held to be invalid, illegal or unenforceable, in any respect, then such provision will be given no effect by the Parties and shall not form part of this Agreement. To the fullest extent permitted by applicable law and if the rights or obligations of any Party will not be materially and adversely affected, all other provisions of this Agreement shall remain in full force and effect and the Parties will use their best efforts to negotiate a provision in replacement of the provision held invalid, illegal or unenforceable that is consistent with applicable law and achieves, as nearly as possible, the original intention of the Parties.
- **12.12. Further Assurance.** Each Party shall perform all further acts and things and execute and deliver such further documents as may be necessary or as the other Party may reasonably require to implement or give effect to this Agreement.
- 12.13. Publicity. Notwithstanding Section 6.1.6, it is understood that the Parties will issue a press release announcing the execution of this Agreement in such form as the Parties shall mutually agree. The Parties agree to consult with each other reasonably and in good faith with respect to the text and timing of any subsequent press releases relating to the Agreement or the activity hereunder prior to the issuance thereof, provided that a Party may not unreasonably withhold consent to such releases, and that either Party may issue such press releases as it determines, based on advice of counsel, are reasonably necessary to comply with laws or regulations or for appropriate market disclosure or which are consistent with information disclosed in prior releases properly made hereunder.
- 12.14. Relationship of the Parties. The status of a Party under this Agreement shall be that of an independent contractor. Nothing contained in this Agreement shall be construed as creating a partnership, joint venture, or agency relationship between the Parties or, except as otherwise expressly provided in this Agreement, as granting either Party the authority to bind or contract any obligation in the name of or on the account of the other Party or to make any statements, representations, warranties, or commitments on behalf of the other Party. All Persons employed by a Party or any of its Affiliates shall be employees of such Party or its Affiliates and not of the other Party or such other Party's Affiliates and all costs and obligations

incurred by reason of any such employment shall be for the account and expense of such Party or its Affiliates, as applicable.

IN WITNESS WHEREOF, duly authorized representatives of the Parties have duly executed this Agreement to be effective as of the Effective Date.

FOREST LABORATORIES, INC. MICROBIA, INC.

By: /s/ Howard Solomon By: /s/ Peter Hecht

Name: Howard Solomon Name: Peter Hecht

Title: Chairman Title: CEO

# **EXHIBIT 1.30**

**Development Plan** 

Linaclotide Development Plan - Final 8/20/07

Duration\* Status Timing in Relation to Clinical Development Program for CC and IBS-C

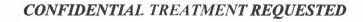
General Program Assumptions: The plans described here reflect the current view for the major studies and program activities that are to be completed for the development of linaclotide. This plan does not reflect all the studies that are to be done to support the program, since data, regulatory requirements and mutual objectives for the development and commercialization of linaclotide may drive the need for additional studies.

API Supply			
и говрију			
Qualify 2nd PPL site	9 - 12 months	Ongoing	pre-PHASE III
Registration Batches/Stability for both sites	6 - 9 months	Planned	PHASE III
Qualify 2nd Supplier - Chemical Characterization/Purity Profile	TBD 3 months	Ongoing Planned	PHASE IIIb/IV
ncorporate alternate technologies (e.g. spray drying)	TBD	Planned	post-PHASE III
Pharmaceutical Development			
Studies to support Environmental Assessment Section of NDA	TBD	Possible	PHASE III
Phase III Formulation Development Stable at room temperature w/ 3 month stability data)	9 - 12 months	Ongoing	PHASE III
Fechnology transfer (analytical/process)	3 months	Planned	PHASE III/IIIb/IV
Manufacturing/Packaging/Distribution for Phase III/IIIb/IV Studies Clinical Supplies)	3 - 6 months	P'anned	PHASE III/IIIb/IV
Define Final Commercial Product (tablet/capsule size, color, imprints/logos, backaging including samples)	TED	P'anned	PHASE III
Stability studies (e.g. Reg batches/shipping/patient use/bulk)	TED	Planned	PHASE III/IIII/IV
Development of Pediatric Formulation	TED	Possible	pre-PHASE IV
Pharmacology			



## Linaclotide Development Plan - Final 8/20/07

	Duration*	Status	Timing in Relation to Clinical Development Program for Co and IBS-C			
General Program Assumptions: The plans described here reflect the current view for the major studies and program activities that are to be completed for the development of linaclotide. This plan does not reflect all the studies that are to be done to support the program, since data, regulatory requirements and mutual objectives for the development accommercialization of linaclotide may drive the need for additional studies.						
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evelopment of Pediatric Formulation	TBD	Possible	pre-PHASE IV			
harmacology						



3

#### Linaclotide Development Plan - Final 8/20/07

Duration\*

Status

Timing in Relation to Clinical Development Program for CC and IBS-C

#### Clinical Pharmacology

Clinical Pharmacology Assumptions: Linaclotide levels in human plasma are undetectable; therefore, traditional Clinical PK Studies are not possible. However, the effects of linaciotide on the PK of other drugs may be measured if warranted. The selection of which drug-drug interaction studies to be conducted will be based upon FDA requirements and determined by consensus by Microbia and Forest. The FDA has requested that Microbia conduct a QTc Prolongation Study, so this is planned.

MCP-103-103, A Randomized, Open-Label, Two-Perlod, Two-Sequence, Crossover Trial of Oral Linaciotide Acetate Administered to Healthy Volunteers Under Fed and

**Fasting Conditions** Design: Open-label, randomized, single-center, two-period, crossover Phase I study Dose Groups: 300ug x 7 days x 2 periods (with a single 3000ug dose on final day) Duration: 14-day crossover period 1 (7-day pre-treatment + 7-day treatment at 300ug), 21day washout, 15-day crossover period 2 (7-day pre-treatment + 7-day treatment at 300ug +

1-day at 3000ug) # of Patients: 20 randomized (to get 16 complete)

Clinical Pharmacology (QTc Prolongation Study) - TBD

Drug Interaction Study with Commonly Administered Concomitant Medications and/or Medications Which May Be Affected By the Mechanism of Action of Linaclotide - TBD

\* Duration for clinical pharmacology studies reflect first informed consent signed through final report

#### 8 months

TBD

TBD

Ongoing

Planned

Possible

PHASE III

PHASE IIb

#### Clinical

Clinical Assumptions: The plan outlined is based upon current knowledge in the program. Plans may change based upon future clinical data and by mutual agreement between Forest and Microbia. Pivotal Phase 3 efficacy study timelines are based upon the use of central recruitment to enroll patients and paper CRFs for data entry. Patients will be enrolled based upon Rome II criteria for CC and IBS-C unless required by FDA to use Rome III. A 3rd Phase 3 trial in IBS-C may be considered pending results from Phase 2b; this trial could be identical to the other Phase 3 trials for risk mitigation, or alternatively, could extend efficacy to 6 months, evaluate intermittent dosing and/or dose titration, assess efficacy in male patients, etc. Patients may roll-over following the randomized withdrawal period (study #1) or directly after completing the randomized treatment period (study #2) from pivotal Phase 3 CC or IBS-C studies into a single long-term safety study (LTSS). Screen failures and Pre-treatment failures from the pivotal Phase 3 CC and IBS-C studies may also enter the LTSS If inclusion criteria are met. Additional sites will be selected to enroll patients de novo into the LTSS (these sites will not participate in the efficacy trials).

#### Chronic Constipation (CC)

MCP-103-201, A Randomized, Multicenter, Double-Blind, Placebo-Controlled, Dose-Range-Finding, Parallel-Group, Phase 2 Trial of Oral Linaclotide Acetate Administered to Patients with Chronic Constipation

19 months

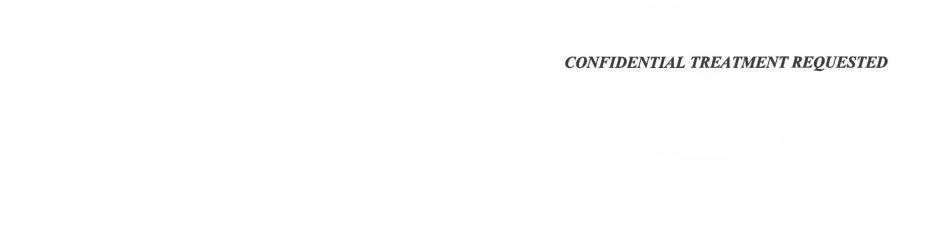
Ongoing

PHASE IIb

Timing in Relation to Clinical Development Program for CC Duration\* Status and IBS-C Design: Double-blind, multicenter, randomized, placebo-controlled, parallel-group Dose groups: 75ug, 150ug, 300ug, 600ug Oral Linaclotide Acetate or Placebo Duration: 2-week pre-treatment baseline period, 4-week treatment period (once daily dosing for 28 days (drug taken on empty stomach and at least 30 minutes prior to patient's first meal of the day)), 2-week post-treatment period # of patients: 60/group (N=300), 60 study centers Pivotal Efficacy/Safety Study #1 in Chronic Constipation (CC) Planned PHASE III 22 months Design: Double-blind, randomized, placebo-controlled, parallel-group Dose groups: 1 or 2 doses Oral Linaclotide Acetate, Placebo Duration: 2-week baseline period, 12-week treatment period, 4-week post-treatment period with randomized withdrawal # of patients: 200-300/group (N=600) Primary endpoint CSBM overall responder rate Pivotal Efficacy/Safety Study #2 In Chronic Constipation (CC) 22 months Panned Design: Double-blind, randomized, placebo-controlled, parallel-group Dose groups: 1 or 2 doses Oral Linaclotide Acetate, Placebo Duration: 2-week baseline period, 12-week treatment period # of patients: 200-300/group (N=600) Primary endpoint: CSBM overall responder rate Irritable Bowel Syndrome with Constipation (IBS-C) MCP-103-202, A Randomized, Multicenter, Double-Blind, Placebo-Controlled, Dose-Range-Finding, Parallel-Group, Phase 2 Trial of Oral Linaciotide Acetate PHASE IIb 14 months Ongoing Administered to Patients with Irritable Bowel Syndrome with Constipation Design: Double-blind, multicenter, randomized, placebo-controlled, parallel-group Dose groups: 75ug, 150ug, 300ug, 600ug Oral Linaclotide Acetate or Placebo Duration: 2-week pre-treatment period (once daily dosing for 12 weeks (drug taken on empty stomach and at least 30 minutes prior to patient's first meal of the day)), 2-week posttreatment period # of patients. 80/group (N=400) 100 study centers Pivotal Efficacy/Safety Study #1 In Irritable Bowel Syndrome with Constipation 22 months Planned (IBS-C) PHASE III Design: Double-blind, randomized, placebo-controlled, parallel-group Dose groups: 1 or 2 doses Oral Linaclotide Acetate, Placebo Duration: 2-week baseline period, 12-week treatment period, 4-week post-treatment period with randomized withdrawal

Linaclotide Development Plan - Final 8/20/07

# of patients: 200-300/group (N=600)
Primary Endpoint CSBM overall responder rate



Linaclotide Development Plan - Final 8/20/07 Timing in Relation to Clinical Development Program for CC Duration\* Status and IBS-C Pivotal Efficacy/Safety Study #2 in Irritable Bowel Syndrome with Constipation 22 months P'anned (IBS-C) Design: Double-blind, randomized, placebo-controlled, parallel-group Dose groups: 1 or 2 doses Oral Linaclotide Acetate, Placebo Duration: 2-week baseline period, 12-week treatment period # of patients: 200-300/group (N=600) Primary endpoint CSBM overall responder rate OPTIONAL 3RD STUDY (necessity and design TBD):
Pivotal Efficacy/Safety Study #3 in Irritable Bowel Syndrome with Constipation TBD Possible (IBS-C) Opioid Induced Constipation (OIC) MCP-103-203, A Randomized, Double-blind, Placebo-controlled, Parallel-group Trial of Oral Linaclotide Acetate Administered for 14 Days to Patients with Opioid-induced 13 months Planned Constipation PHASE III Design: Double-blind, randomized, placebo-controlled, parallel-group Dose groups: 75ug, 150ug, 300ug, 600ug Oral Linaclotide Acetate or Placebo Duration: 1-week pre-treatment period, 2-week treatment period, 1-week post-treatment period # of patients: 20/group (N=100) Primary Endpoint SBM frequency Long Term Safety Studies Open Label Study (de novo and extension patients) in Chronic Constipation (CC) and 24 months Planned PHASE III Irritable Bowel Syndrome with Constipation (IBS-C) Design: Open-Label Dose groups: Oral Linaclotide Acetate (high dose vs. 2 doses TBD) Duration: 52 weeks # of patients: N=1500 (estimated enrollment based on ~50% of patients rolling-over from pivotal efficacy trials for a total of 1200 plus ~300 de novo patients. This will ensure enough safety data to include =600 for 6 months, =200 for 12 months in the NDA at the time of submission) Phase IIIb/IV Comparator - TBD (IBS-C, CC, or Both?) TBD Possible PHASE IIIb/IV Design: Double-blind, parallel-group Dose groups: Oral Linaclotide Acetate, Placebo, Comparator Elderly - TBD (CC?) TBD Possible Design: Double-billind, parallel-group



Linaclotide Development Plan - Final 8/20/07

Dose groups: Oral Linaclotide Acetate, Placebo	Duration*	Status	Timing in Relation to Clinical Development Program for Co and IBS-C
Switch Study - TBD (IBS-C?) Design: Partial responders to PEGs or Amitizia switch over to Oral Linaclotide Acetate Dose groups: Oral Linaclotide Acetate	TBD	Possible	
Male Study - TBD (Both IBS-C and CC to be discussed) <u>Design:</u> Double-blind, parallel-group <u>Dose Groups:</u> Oral Linaclotide Acetate, Placebo	TBD	Possible	
Special Populations - Pediatric			
Pose Range finding Pharmacodynamic Study in Pediatric Subjects	8 months	Planned	PHASE IIIb / IV
Plvotal Efficacy - CC <u>Design:</u> Double-blind, parallel-group <u>Dose groups:</u> 1 or 2 doses Oral Linaclotide Acetate, Placebo <u>Duration</u> : 12 weeks <u>f of patients</u> : TBD	TBD	Planned	PHASE IIIb / IV
Pivotal Efficacy - IBS-C <u>lesign:</u> Double-blind, parallel-group <u>lose groups:</u> 1 or 2 doses Oral Linaclotide Acetate, Placebo <u>puration:</u> 12 weeks <u>of patients</u> : TBD	TBD	Possible	
Long-Term Safety - CC and IBS-C <u>Design:</u> Open-label <u>Dose groups:</u> Oral Linaclotide Acetate <u>Duration:</u> 40 weeks <u># of patients:</u> TBD	TBD	Planned	

#### \* Duration for all clinical studies reflect first informed consent signed through Clinical Study Report (CSR)

#### Regulatory

## Target Indications and Usage Language at approval:

- Linaclotide is indicated for the treatment of Chronic Constipation in the adult
- population
   Linaclotide is indicated for treatment of Irritable Bowel Syndrome with Constipation (IBS-C) in the adult population

#### Plans for future agency meetings:

## Linaclotide Development Plan - Final 8/20/07

Duration\*

Status

Timing in Relation to Clinical Development Program for CC and IBS-C

- EOP2 meeting for CC & IBS-C Indications
- FDA has tentatively agreed to hold 2 EOP2 meetings, one for each indication
- CMC EOP2 meeting date TBD based on P3 formulation
   Pre-NDA meeting for CC & IBS-C
- Other meetings as needed

#### Issues for discussion at EOP2 Meeting:

- · Phase 3 endpoints, duration, design
- · Safety database, patient numbers/exposure
- Draft labeling for IBS-C and CC
- Special populations (pediatric, renal insufficiency, etc)
- Request to defer the conduct of pediatric studies post approval will be made. The potential for a partial waiver (for pediatric patients under the age of X) will be discussed
- · Pharmacology/toxicology data in support P3 initiation

#### NDA submission:

- One NDA for both CC and IBS-C Indications
- Request for small-business user-fee waiver
- · Standard review is likely

#### Exclusivity:

- Hatch-Waxman
- Pediatric

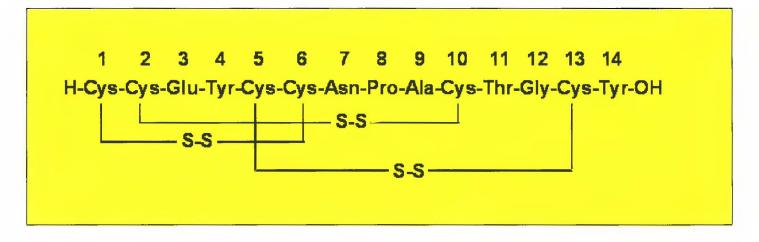
## **SCHEDULE 1.5**

## **Existing Backup Compounds**

[MM-435160 NSSNYCCELCCNPACTGCYDF MM-435161 CCELCCNPACTGCYDF MM-435162 CCEYCCNPACTGCYDF MM-419447 CCEYCCNPACTGC]

## **SCHEDULE 1.47**

## **Initial Compound**



#### **SCHEDULE 4.1.1**

Certain Clinical and Non-Clinical Development and Regulatory Responsibilities for Forest-Microbia Development of the Product in the Field in the Territory

## [Clinical Responsibilities

Microbia and Forest will be jointly responsible for Phase III safety and efficacy and clinical pharmacology studies, with Microbia being responsible for at least two Phase III studies and each Party being responsible for at least one CC and one IBS-C study. The Phase IV study program will be subject to approval by the JDC, subject to input from the JCC.

## Non-Clinical Responsibilities

Remaining preclinical GLP studies required for a US NDA are either currently underway or planned and will continue to be overseen and managed by Microbia, subject to oversight by the JDC. The responsibility for any additional preclinical studies required by the FDA or determined to be appropriate by the JDC will be assigned by the JDC. Microbia will be responsible for determining which preclinical studies are conducted in support of product registration outside of the Territory. Each Party will keep the other informed of preclinical studies being conducted or proposed to be conducted, whether within or outside the Territory. Microbia will remain responsible for submitting preclinical safety data to the US IND and will prepare reports and summaries for the NDA (eCTD).

## Regulatory Responsibilities

## IND

Forest will be authorized by Microbia to submit IND safety information and protocol amendments on behalf of Microbia (pursuant to item no. 17 on FDA Form 1571 or equivalent mechanism) and Microbia will remain authorized to submit equivalent information to the FDA. Microbia will promptly take such steps as may be reasonably required to provide Forest with the authorization required to submit data to the FDA on behalf of Microbia and to communicate with the FDA as appropriate in light of Forest's Development and regulatory responsibilities hereunder. The proposed submission plan is as follows:

<u>Information Amendments (Preclinical study reports, CMC documentation and Clinical study reports) will be:</u>

- prepared by Forest or Microbia (depending on information to be submitted)
  - o <u>Information amendments will be reviewed and approved by both Forest and Microbia prior to submission</u>
- submitted by Microbia, with a copy for Forest

<u>Protocol amendments (new protocols, changes in a protocol and new investigator information)</u> will be:

- prepared by Microbia or Forest based on who is conducting the study
  - o all new protocols and protocol changes will be reviewed and approved by both Microbia and Forest prior to submission
  - o <u>investigator information may be submitted prior to review of the information by</u> the other Party
- <u>submitted by Microbia or Forest based on who is conducting the study, with a copy for the other Party</u>

## **IND Safety Reports:**

- Forest will maintain a safety database for all safety data with respect to Product Development and will prepare and submit IND Safety Reports. Forest will provide Microbia with a copy of all IND Safety Reports.
  - o Both Parties will review all SAEs, regardless of causality and expectedness. If there is disagreement whether an SAE requires expedited reporting, the decision will be based on the more conservative of the two opinions. All information in the safety database will be made available to Microbia and Microbia will have the right to share safety information regarding the Product with its partners and collaborators developing or commercializing the Product or Collaboration Compound outside the Territory.

Annual Reports and General Correspondence (e.g. requests for meetings, response to FDA request for information, etc.) will be:

- prepared jointly
  - o annual reports and general correspondence will be reviewed and approved by both Microbia and Forest prior to submission
- submitted by Microbia, with a copy for Forest

Correspondence from FDA will continue to be received by Microbia. Forest will be copied on all correspondence from FDA.

#### **FDA Meetings**

End-of-Phase II meeting – representation from both companies with Microbia leading the discussions, subject to coordination with Forest.

<u>Pre-NDA</u> and other FDA meetings – representation from both Parties with leadership to be mutually agreed upon prior to the meeting.

<u>Labeling Negotiation meetings/teleconferences – representation from both Parties with Forest leading the discussions, subject to coordination with Microbia.</u>

## **NDA**

Preparation review and approval of modules – joint. It is anticipated that the Party performing or taking the lead in specific Development activities will take the lead in preparing the corresponding modules of the NDA and the JDC will determine other NDA preparation responsibilities where both Parties have responsibilities, with due regard to the availability of resources and cost effectiveness.

Publishing of NDA Documents – led by Forest with Microbia participation

Each Party will have a full copy of the NDA. Microbia will have the full right to use the modules for submissions outside the Territory and to provide copies of the modules to its collaborators and partners developing or commercializing the Product or Collaboration Compound outside the Territory.

#### Submission – Microbia

Forest will be copied on all submissions (including amendments) and correspondence to and from the FDA. Responsibility to prepare responses to questions prior to NDA acceptance will be based on the question. Microbia will submit response. No submission shall be made without the prior consent of both Parties as provided by Section 4.2.2.

## Post NDA Acceptance Responsibilities

Once the NDA has been accepted for filing, ownership will be transferred to Forest (21 CFR 314.72) and the IND will be retained by Microbia. The ownership of subsequent IND's created pursuant to this Agreement will be determined by the JDC.

Forest will be responsible for maintaining the NDA (e.g., annual reports, submissions to DDMAC, Safety Reporting, etc.) with support from Microbia as needed. Decisions regarding the submission of new NDA's, supplements or amendments to the initial NDA will be made jointly.

Pharmacovigilance / Call Center — Post-marketing (spontaneous) AE database maintenance and safety reporting will be managed by Forest. Both companies will be responsible for reviewing safety data and FDA submissions (e.g., 15-day reports and PSURs). Both companies will also participate in the annual review of the package insert. All such activities will be governed by the terms of the Pharmacovigilance Agreement referred to in Section 4.3.

Advertising and promotion activities – There will be joint responsibility for the preparation, review and approval of promotional material as well as dossiers for formularies/managed care and sales rep training material, subject to the oversight of the JCC.

Medical Affairs – Subject to the oversight of the JDC in light of the specific activities involved, there will be joint Microbia and Forest participation in medical affairs activities (e.g., Q and A

generation, review and approval; CME program; Phase IV study plan approval and execution (including funding); Phase IV commitments (including pediatric studies); publication planning and approval, ESA's).]

#### **SCHEDULE 4.5.3**

## **Promotional Obligations**

- [(a) Sales Force. The JCC will determine the number of physicians to be on the call plan. call frequency and other matters necessary to determine the size of the Microbia sales force to be utilized for Promotion pursuant to the Agreement. Each sales representative shall have a sales territory that allows such sales representative to perform a reasonable number of Details within a reasonable geographic area (i.e., without overly-burdensome travel requirements). During the pre-launch period, Microbia shall use its Commercially Reasonable Efforts to engage and organize the Microbia sales force. The Microbia sales force will be organized by Microbia under the general recommendations and supervision of the JCC as to numbers and qualifications of sales representatives and field-based sales managerial personnel and the timing of hiring in light of the then-current Commercialization Plan. Such sales representatives shall have qualification and experience at least comparable to Forest's sales representatives and shall be entitled to incentive compensation with respect to the marketing of the Product on a basis not materially less favorable to the Product than provided by Forest to its sales representatives. The Microbia sales force shall be comprised of full time employees of Microbia and shall not be delegated to a contract sales organization. Upon Forest's request, Microbia shall permit Forest to review and audit Microbia's sales force activities for purposes of assuring compliance with the provisions hereof and the standards set forth in Section 4.5.2.
- (b) Training Materials and Sessions. The Parties will jointly develop Product specific training materials and arrange for provision of such materials to their sales forces. Forest will permit Microbia sales representatives to participate in training sessions of the Forest sales force in Product-specific sales skills with respect to the Product and the indications for the Product and will provide reasonable advance notice to Microbia of scheduled training events. As the costs of sales force training are included in the FTE Rate for sales representatives, and accordingly will be included in payments to Microbia with respect to FTE Costs, Microbia shall reimburse any incremental costs incurred by Forest in providing such training to Microbia's sales representatives. Without limiting the generality of the foregoing, the Parties intend that the Microbia sales force will participate in the initial Product launch and subsequent sales force meetings to the extent related to the Product.
- (c) Promotional Materials. Forest shall provide Microbia with sales and promotional materials reasonably sufficient to permit Microbia to perform Detailing calls in a manner consistent with the Detailing calls performed by the Forest sales force. The project managers of each Party will share with one another any such materials, and no such materials may be utilized until completion of Forest's regulatory and compliance review.
- (d) Sampling. Forest shall provide Microbia with Product samples reasonably sufficient to permit Microbia to perform Detailing calls in accordance with the Commercialization Plan. Microbia shall be responsible for accounting for sample distribution by the Microbia sales force and shall maintain all records with respect to sample distribution as required by applicable laws and regulations. Within thirty (30) days after the end of each month, Microbia shall provide to

Forest a written report summarizing samples distributed by the Microbia sales force for such calendar month. In addition, Microbia shall ensure, through appropriate routine monitoring and auditing standards which conform with current good industry practices, that sampling of the Product is carried out by Microbia in a manner which is in compliance with all Applicable Laws. Microbia shall immediately advise Forest of its discovery of any act or omission of Microbia regarding sample distribution that could violate or require reporting under applicable law. Forest shall be solely responsible for the filing of any necessary reports to FDA in connection with sampling. Within thirty (30) days after any termination of Microbia's participation in the promotion of the Product, Microbia shall return, or otherwise dispose of in accordance with written instructions from Forest, all remaining samples and will provide Forest with a certified statement that all remaining samples have been returned or otherwise properly disposed of in accordance with Forest's instructions and that Microbia is no longer in possession or control of any samples in any form or fashion.]

## **SCHEDULE 5.2.2(i)**

**Stock Purchase Agreement** 

# FORM OF SERIES G CONVERTIBLE PREFERRED STOCK PURCHASE AGREEMENT

**BY AND AMONG** 

MICROBIA, INC.

**AND** 

THE SEVERAL PURCHASERS NAMED IN EXHIBIT A

[Date]

#### SERIES G CONVERTIBLE PREFERRED STOCK PURCHASE AGREEMENT

This SERIES G CONVERTIBLE PREFERRED STOCK PURCHASE AGREEMENT (this "Agreement") is made and entered into as of [Date], by and among MICROBIA, INC., a Delaware corporation (the "Company"), and each of those persons and entities, severally and not jointly, whose names are set forth on the Schedule of Purchasers attached hereto as Exhibit A (which persons and entities are hereinafter collectively referred to as "Purchasers" and each individually as a "Purchaser").

#### RECITALS

WHEREAS, the Company has authorized the sale and issuance of an aggregate of up to [•] shares of its Series G Convertible Preferred Stock (the "Series G Stock");

WHEREAS, the Purchasers desire to purchase the Shares on the terms and conditions set forth herein; and

WHEREAS, the Company desires to issue and sell such Shares to Purchasers on the terms and conditions set forth herein.

#### **AGREEMENT**

**Now, Therefore**, in consideration of the foregoing recitals and the mutual promises hereinafter set forth, the parties hereto agree as follows:

#### 1. AGREEMENT TO SELL AND PURCHASE.

1.1 Authorization of Shares. On or prior to the Initial Closing (as defined in Section 2.1 below), the Company shall have duly authorized (a) the sale and issuance to Purchasers of up to [•] shares of its Series G Stock (the "Shares") and (b) the issuance of such shares of Common Stock to be issued upon conversion of the Shares (the "Conversion Shares"). The Shares and the Conversion Shares shall have the rights, preferences, privileges and restrictions set forth in the Eighth Amended and Restated Certificate of Incorporation of the Company, in the form attached hereto as Exhibit B (the "Restated Charter"). The Company has, or prior to the Initial Closing will have, adopted and filed the Restated Charter with the Secretary of State of the State of Delaware.

## 1.2 Sale and Purchase.

- (a) Initial Shares. Subject to the terms and conditions hereof, at the Initial Closing (as defined in Section 2.1) the Company hereby agrees to issue and sell to each Purchaser listed in Part I of Exhibit A (the "Initial Purchasers"), severally and not jointly, and each such Purchaser agrees to purchase from the Company, severally and not jointly, the number of Shares (the "Initial Shares") set forth opposite such Purchaser's name on Exhibit A, at a purchase price of [twelve dollars] (\$[12.00]) per share. The Company's agreement with each of the Purchasers is a separate agreement, and the sale of Shares to each of the Purchasers is a separate sale.
- (b) Additional Shares. If less than all of the authorized number of shares of Series G Stock are sold at the Initial Closing, then, subject to the terms of this Agreement, at one or more Additional Closings (as defined in Section 2.2), the Company may issue and sell up to the balance of the authorized but unissued shares of Series G Stock (the "Additional Shares") at a purchase price of [twelve dollars] (\$[12.00]) per share to such

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additional purchasers (the "Additional Purchasers") as the majority of the Board of Directors may approve. The Company and each Additional Purchaser shall execute the counterpart signature page for Additional Closings attached hereto, and upon such execution and delivery, each such counterpart shall be deemed a part of this Agreement and Exhibit A shall automatically be amended to reflect the Additional Shares purchased in such Additional Closing.

The Initial Shares and the Additional Shares are collectively referred to hereinafter as the "Shares." The Initial Purchasers and the Additional Purchasers are collectively referred to hereinafter as the "Purchasers."

## 2. CLOSING, DELIVERY AND PAYMENT.

- 2.1 Initial Closing. The closing of the sale and purchase of the Initial Shares under this Agreement (the "Initial Closing") shall take place at 10:00 a.m. on the date hereof, upon the satisfaction of the closing conditions set forth in Section 5.1 below, at the offices of Ropes & Gray LLP, One International Place, Boston, Massachusetts 02110, or at such other time or place as the Company and Purchasers may mutually agree (such date is hereinafter referred to as the "Initial Closing Date"). If at the Initial Closing any of the conditions specified in Section 5.1 shall not have been fulfilled, each of the Initial Purchasers shall, at his, her or its election, be relieved of all of his, her or its obligations under this Agreement without thereby waiving any other rights such Initial Purchaser may have by reason of such failure or such non-fulfillment.
- Additional Shares under this Agreement (each, an "Additional Closing"), shall take place at such time, date, and place as the Company and each Additional Purchaser may mutually agree (each such date is hereinafter referred to as an "Additional Closing Date"); provided, however, that any Additional Closings under the terms of this Agreement shall occur no later than sixty days after the date of the Initial Closing (the "Additional Closing Deadline"), provided further that, the Additional Closing Deadline may be extended by mutual agreement between the Company and the holders of a majority of the then outstanding shares of Series G Stock with respect to the issuance of any Additional Shares under this Agreement or otherwise. If at any Additional Closing any of the conditions specified in Section 5.1 shall not have been fulfilled, each of the Additional Purchasers shall, at his, her or its election, be relieved of all of his, her or its obligations under this Agreement without thereby waiving any other rights such Additional Purchaser may have by reason of such failure or such non-fulfillment.
- **2.3 Delivery.** At the Initial Closing and each Additional Closing (the Initial Closing and each Additional Closing, a "*Closing*"), subject to the terms and conditions hereof, the Company will deliver to each Purchaser a certificate representing the number of Shares to be purchased at such Closing by such Purchaser, against payment of the purchase price therefor by check, wire transfer made payable to the order of the Company, or any combination of the foregoing.
- **2.4** Use of Proceeds. The Company shall use the proceeds from the sale of the Shares for product development and for general working capital purposes.

## 3. REPRESENTATIONS AND WARRANTIES OF THE COMPANY.

Except as set forth in the Schedule of Exceptions attached hereto as **Exhibit E** delivered by the Company to the Purchasers at the Initial Closing and at any Additional Closing, the Company hereby represents and warrants to each Purchaser as of the date of this Agreement as follows:

Organization, Good Standing and Qualification. The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. The Company has all requisite corporate power and authority to own and operate its properties and assets, to carry on its business as presently conducted and as presently proposed to be conducted, to execute and deliver this Agreement, the Seventh Amended and Restated Investors' Rights Agreement in the form attached hereto as Exhibit C (the "Investors' Rights Agreement"), the Fourth Amended and Restated Voting Agreement in the form attached hereto as Exhibit D (the "Voting Agreement" and together with the Investors' Rights Agreement, the "Related Agreements"), to issue and sell the Shares and the Conversion Shares, and to carry out the provisions of this Agreement, the Related Agreements and the Restated Charter. The Company is duly qualified and is authorized to do business as a foreign corporation and is in good standing in all jurisdictions listed in the Schedule of Exceptions in which the nature of its activities and of its properties (both owned and leased) makes such qualification necessary, except for those jurisdictions in which failure to so qualify would not have a material adverse effect on the business, assets, properties, operations, prospects or financial condition of the Company (a "Material Adverse Effect"). The Company has furnished to each Purchaser who has so requested in writing, true and complete copies of its Seventh Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation") and By-Laws as presently in effect.

**3.2 Subsidiaries.** Except as set forth in the Schedule of Exceptions, the Company has no subsidiaries and does not own or control, directly or indirectly, any equity security of any corporation or any other interest in any other corporation, general or limited partnership, joint venture association, business trust or other business entity. The Company is not a participant in any joint venture, partnership or similar arrangement.

## 3.3 Capitalization; Voting Rights.1

The authorized capital stock of the Company, immediately prior to the Initial Closing after giving effect to the Restated Charter, will consist of [80,932,230] shares of Common Stock, par value \$0.001 per share, 6,934,807 shares of which are issued and outstanding and 9,677,915 shares of which are reserved for future issuance to employees pursuant to the Company's 1998 Stock Option Plan, 2002 Stock Incentive Plan, 2002 California Stock Incentive Plan and 2005 Stock Incentive Plan (collectively, the "Stock Incentive Plans") and [63,843,741] shares of Preferred Stock, par value \$0.001 per share, 8,904,567 of which are designated Series A Preferred Stock, all of which are issued and outstanding 7,419,355 of which are designated Series B Preferred Stock, all of which are issued and outstanding, 6,401,523 of which are designated Series C Stock, all of which are issued and outstanding, 12,618,296 of which are designated as Series D Stock, all of which are issued and outstanding, 20,500,000 of which are

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<sup>&</sup>lt;sup>1</sup> Capitalization figures are current as of the date of the Master Collaboration Agreement between the Company and Forest Laboratories.

designated as Series E Stock, 19,633,531 of which are issued and outstanding, 8,000,000 of which are designated as Series F Stock, 8,000,000 of which are issued and outstanding, and [•] of which are designated as Series G Stock, none of which are issued and outstanding (collectively, the "*Preferred Stock*"). All issued and outstanding shares of the Company's capital stock (a) have been duly authorized and validly issued, (b) are fully paid and non-assessable, and (c) were offered, issued, sold and delivered in compliance with all applicable federal and state securities laws. The rights, preferences, privileges and restrictions of the Shares are as stated in the Restated Charter. Each series of Preferred Stock is convertible into Common Stock on a one-forone basis. The Conversion Shares have been duly and validly reserved for issuance.

- Other than the 9,677,915 shares reserved for issuance under the (a) Company's Stock Incentive Plans, and except as provided in the Restated Charter and the Investors' Rights Agreement or as set forth in the Schedule of Exceptions, (i) no subscriptions, warrants, options, convertible securities or other rights (contingent or otherwise) to purchase or acquire (including conversion or preemptive rights and rights of first refusal) any shares of capital stock of the Company are authorized or outstanding, (ii) the Company has no obligation (contingent or otherwise) to issue any subscription, warrant, option, convertible security or other such right (including conversion or preemptive rights and rights of first refusal) or to issue or distribute to holders of any shares of its capital stock any evidences of indebtedness or assets of the Company, and (iii) the Company has no obligation (contingent or otherwise) to purchase, redeem or otherwise acquire any shares of its capital stock or any interest therein or to pay any dividend or make any other distribution in respect thereof, and (iv) no stock appreciation, phantom stock or similar rights with respect to the Company are authorized or outstanding. Except as contemplated by this Agreement, the Related Agreements or in the Schedule of Exceptions, there are no agreements or proxies, written or oral, between the Company and any holder of its capital stock, or, to the best knowledge of the Company, among any holders of its capital stock, relating to the acquisition, disposition or voting of the capital stock of the Company.
- (b) When issued in compliance with the provisions of this Agreement and the Restated Charter, the Shares and the Conversion Shares will be validly issued, fully paid and nonassessable, and will be free of any liens or encumbrances (other than liens and encumbrances created by the Purchasers); provided, however, that the Shares and the Conversion Shares may be subject to restrictions on transfer under state and/or federal securities laws as set forth herein or as otherwise required by such laws at the time a transfer is proposed. The sale of the Shares and the subsequent conversion of the Shares into Conversion Shares are not and will not be subject to any preemptive rights or rights of first refusal that have not been properly waived or complied with on or prior to the Initial Closing.
- (c) Attached as **Exhibit G** hereto is a true and complete list of the securityholders of the Company, showing the number of shares of Common Stock, Preferred Stock or other securities of the Company held by each securityholder as of the date of this Agreement and, in the case of options, warrants and other convertible securities, the exercise price thereof and the number and type of securities issuable thereunder.
- 3.4 Authorization; Binding Obligations. All corporate action on the part of the Company, its officers, directors and stockholders necessary for the authorization of this

Agreement and the Related Agreements, the performance of all obligations of the Company hereunder and thereunder at each Closing and the authorization, sale, issuance and delivery of the Shares pursuant hereto and the Conversion Shares pursuant to the Restated Charter has been taken or will be taken prior to the Initial Closing. This Agreement and the Related Agreements have been duly executed and delivered by the Company and constitute the valid and binding obligations of the Company enforceable in accordance with their respective terms, except (a) as limited by applicable bankruptcy, insolvency, reorganization, moratorium or other laws of general application affecting enforcement of creditors' rights, (b) general principles of equity that restrict the availability of equitable remedies, and (c) to the extent that the enforceability of the indemnification provisions in Section 2.9 of the Investors' Rights Agreement may be limited by applicable laws.

- Purchaser a complete and correct copy of (i) the audited balance sheet of the Company as of December 31, 200\_, and the related, audited statements of income, changes in stockholders' equity and cash flows for the fiscal year then ended, and (ii) the unaudited balance sheet of the Company as of \_\_\_\_\_\_ (the "Statement Date"), and the related, unaudited statements of income and cash flows for the fiscal year then ended (collectively, the "Financial Statements"). The Financial Statements, together with the notes thereto, were prepared in accordance with generally accepted accounting principles applied on a basis consistent with prior periods, are complete and correct in all material respects and present fairly the financial condition and position of the Company as of their respective dates; provided, however, that the unaudited Financial Statements are subject to normal recurring year-end audit adjustments (which will not be material), and do not contain all footnotes required under generally accepted accounting principles.
- 3.6 Liabilities. Except as set forth in the Schedule of Exceptions, the Company has no material liabilities and, to the best of its knowledge, knows of no material contingent liabilities not disclosed in the Financial Statements, except current liabilities incurred in the ordinary course of business which are not, either individually or in the aggregate, material to the business, assets, properties, operations, prospects or financial condition of the Company.
- 3.7 Absence of Changes. Except as set forth in the Schedule of Exceptions, since the Statement Date, there has not been:
- (a) any change in the business, assets, properties, operations, prospects or financial condition of the Company, except changes in ordinary course of business that have not been, either individually or in the aggregate, materially adverse;
- **(b)** any change (individually or in the aggregate) in the contingent obligations of the Company by way of guaranty, endorsement (other than endorsement of drafts in the ordinary course of business for the purpose of collection), indemnity, warranty (other than in the ordinary course of business), or otherwise.
- (c) any material loss, destruction or damage to any property of the Company, whether or not insured;

- (d) any waiver by the Company of any valuable right or of any material debt or claim owed to it;
- (e) any satisfaction or discharge of any lien, claim or encumbrance or payment of any obligation by the Company, except in the ordinary course of business or that is not material to the business, assets, properties, operations, prospects or financial condition of the Company;
- **(f)** any material change or amendment to a material contract or arrangement by which the Company or any of its assets or properties is bound;
- **(g)** any change in the compensation paid or payable to any officer, director, employee, consultant, agent or stockholder of the Company (other than compensation increases in the ordinary course of business consistent with past practice, which, individually and in the aggregate, are not material);
- (h) any resignation or termination of any executive officer or other key employee of the Company or material change in the terms and conditions of their employment;
- (i) any loans or advances made to any person, other than ordinary advances for travel expenses;
- (j) any direct or indirect redemption or acquisition of, any capital stock in the Company;
- (k) declared or paid any dividends, or authorized or made any distribution in cash or in kind upon or with respect to any class or series of its capital stock;
- (I) to the Company's knowledge, any other event or condition of any character that has affected, or may affect, materially and adversely, the Company's business or prospects; or
- (m) any agreement or understanding, whether in writing or otherwise, for the Company to take or become subject to any of the actions specified in paragraphs (a) through (l).

## 3.8 Agreements; Action.

- (a) Except for agreements explicitly contemplated hereby, agreements between the Company and its employees with respect to the sale of the Company's Common Stock under the Stock Incentive Plans, and except as set forth in the Schedule of Exceptions, there are no agreements, understandings or proposed transactions between the Company and any of its officers, directors, affiliates or any affiliate thereof.
- **(b)** The Schedule of Exceptions sets forth a list of all agreements, or commitments of any nature (whether written or oral) to which the Company is a party by which it is bound, including without limitation (i) any agreement which requires future expenditures by the Company in excess of \$1,000,000, (ii) the transfer or license of any patent, trademark,

copyright, trade secret or other proprietary right to or from the Company (other than licenses arising from the purchase of "off the shelf" or other standard products), (iii) any employment or consulting agreement in excess of \$100,000, employee benefit, bonus, pension, profit-sharing, stock option, stock purchase or similar plan or arrangement, (iv) any distributor, sales representative or similar agreement, (v) any agreement with any current or former stockholder, officer or director of the Company, or any "affiliate" or "associate" of such persons (as such terms are defined in the rules and regulations promulgated under the Securities Act of 1933, as amended (the "Securities Act"), including without limitation any agreement or other arrangement providing for the furnishing of services by, rental of real or personal property from, or otherwise requiring payments to, any such person or entity, (vi) provisions restricting the development, manufacture or distribution of the Company's products or services, or (vii) indemnification by the Company with respect to infringements of proprietary rights (other than indemnification obligations arising from purchase or sale or license agreements entered into in the ordinary course of business), (viii) provisions restricting the development, manufacture or distribution of the Company's products or services, (ix) any agreement relating to indebtedness for borrowed money, (x) any agreement for the disposition of a material portion of the Company's assets (other than in the ordinary course of business) and (xi) any agreement for the acquisition of the business or shares of another party.

- (c) Except as set forth in the Schedule of Exceptions, the Company has not (i) declared or paid any dividends, or authorized or made any distribution upon or with respect to any class or series of its capital stock or (ii) made any loans or advances to any person, other than ordinary advances for travel expenses.
- (d) For the purposes of subsection (b) above, all indebtedness, liabilities, agreements, understandings, instruments, contracts and proposed transactions involving the same person or entity (including persons or entities the Company has reason to believe are affiliated therewith) shall be aggregated for the purpose of meeting the individual minimum dollar amounts of such subsection.
- (e) All of the contracts, agreements and instruments to which the Company is a party are valid, binding and enforceable in accordance with their respective terms, except for those contracts, agreements and instruments the lack of validity, binding effect or enforceability of which would not have a Material Adverse Effect. The Company has performed all obligations required to be performed by it and is not in default under, or in breach of, nor in receipt of any claim of default or breach under any contract, agreement or instrument, except for such breaches or defaults, which either individually or in the aggregate, would not have a Material Adverse Effect, and the Company does not have any present expectation or intention of not fully performing all such obligations. To the Company's knowledge, no event has occurred which with the passage of time or the giving of notice or both would reasonably be expected to result in a default, breach or event of noncompliance by the Company under any contract, agreement or instrument. The Company has no knowledge of any breach or anticipated breach by the other parties to any contract, agreement or instrument.
- (f) Each Purchaser who has so requested in writing has been supplied with a true and correct copy of each of the written instruments, plans, contracts and agreements and an accurate description of each of the oral arrangements, contracts and agreements that are

referred to on the Schedule of Exceptions pursuant to this Section 3.8, together with all amendments, waivers or other changes thereto.

- (g) The Company is not a party to and is not bound by any contract, agreement or instrument, or subject to any restriction under its Certificate of Incorporation or By-laws that, to its knowledge, adversely affects in any material respect, its business as currently conducted or as proposed to be conducted, or its properties or its financial condition.
- (h) The Company has not engaged in the past three months in any discussion (i) with any representative of any corporation or entity regarding the consolidation or merger of the Company with or into any such corporation or entity or the sale, conveyance or disposition of all or substantially all of the assets of the Company or a transaction or series of related transactions in which more than fifty percent of the voting power of the Company would be disposed of, or (ii) regarding any other form of acquisition, liquidation, dissolution or winding up to the Company.
- 3.9 Obligations to Related Parties. There are no obligations of the Company to officers, directors, stockholders, or employees of the Company other than (a) for payment of salary for services rendered, (b) reimbursement for reasonable expenses incurred on behalf of the Company, and (c) for other standard employee benefits made generally available to all employees (including stock option agreements outstanding under any Stock Incentive Plans). The Company is not a guarantor or indemnitor of any indebtedness of any other person, firm or corporation.
- 3.10 Title to Properties and Assets; Liens, etc. Except as set forth in the Schedule of Exceptions, the Company has good and marketable title to its properties and assets and good title to its leasehold estates, in each case subject to no mortgage, pledge, lien, lease, encumbrance or charge, other than (a) those resulting from taxes which have not yet become delinquent, (b) minor liens and encumbrances which do not materially detract from the value of the property subject thereto or materially impair the operations of the Company, and (c) those that have otherwise arisen in the ordinary course of business. The Company is in compliance with all material terms of each lease to which it is a party or is otherwise bound.

#### 3.11 Patents and Trademarks.

(a) As used in this Agreement, the term "Intellectual Property Rights" with respect to a party means all: (i) patents, patent applications, inventions and designs, and any registration thereof with any agency or authority; (ii) trademarks, service marks, trade names, franchises and copyrights and all registrations and applications to register any of the foregoing with any agency or authority; (iii) trade secrets including all formulae, processes, know-how, technical data, shop rights, and any media or other tangible embodiment thereof and all descriptions thereof; (iv) all other technology and intangible property, including without limitation computer programs in object code or source code form, databases, and documentation and flow charts; and (v) with respect to the Company, any licenses and other rights granted to or by the Company with respect to any of the foregoing, excluding licenses or agreements arising from the purchase of "off the shelf" or standard products.

- The Schedule of Exceptions contains a complete and accurate list of all (i) patents, patent applications, trademarks, copyrights and service marks owned by the Company, identifying the title, name(s) of inventors or author(s), if applicable, filing dates, issue dates, docket or serial numbers, status and countries of issuance, and (ii) licenses granted to or by the Company with respect to any of the Intellectual Property Rights owned or used by the Company. The Company owns or possesses sufficient legal rights to all Intellectual Property Rights necessary for its business as now conducted and as presently proposed to be conducted. To the Company's knowledge, none of the activities conducted by the Company or proposed to be conducted by the Company infringes, violates or constitutes a misappropriation of the Intellectual Property Rights of any other person or entity. In addition, to the Company's knowledge, no other person or entity is infringing, violating or misappropriating any of the Intellectual Property Rights that the Company owns or has licensed. The Company has not received any communications alleging that the Company has violated or, by conducting its business as presently conducted and as proposed to be conducted, would violate any of the Intellectual Property Rights of any other person or entity. To the Company's knowledge, no directors, officers or employees are obligated under any contract (including licenses, covenants or commitments of any nature) or other agreement, or subject to any judgment, decree or order of any court or administrative agency, that would interfere with their duties to the Company or that would conflict with the Company's business as presently conducted and as proposed to be conducted. Neither the execution nor delivery of this Agreement or the Related Agreements, nor the carrying on of the Company's business by the employees of the Company, nor the conduct of the Company's business as presently conducted and as proposed to be conducted, will, to the Company's knowledge, conflict with or result in a breach of the terms, conditions or provisions of, or constitute a default under, any contract, covenant or instrument under which any director, officer or employee, is now obligated. The Company does not believe it is or will be necessary to utilize any inventions, trade secrets or proprietary information of any of its employees made prior to their employment by the Company, except for inventions, trade secrets or proprietary information that have been assigned to the Company and which are disclosed in the Schedule of Exceptions hereto.
- to protect its rights in its Intellectual Property Rights, and (ii) to maintain the confidentiality of its trade secrets, know-how and other confidential Intellectual Property Rights, and to the Company's knowledge, there have been no acts or omissions by the officers, directors, stockholders, employees, consultants and advisors of the Company the result of which would be to materially compromise the rights of the Company to apply for, enforce and otherwise ensure the Company's legal and equitable rights to all its Intellectual Property. Each employee and officer of the Company has executed the Proprietary Information and Inventions Agreement, substantially in the form attached hereto as Exhibit H (the "Proprietary Information and Inventions Agreement"). Each of the Company's consultants has executed a consulting agreement containing provisions relating to proprietary information and inventions substantially similar to those contained in the Proprietary Information and Inventions Agreement.
- 3.12 Compliance with Other Instruments. The Company is not in violation or default of any term of its Certificate of Incorporation or Bylaws, or of any provision of any mortgage, indenture, agreement, instrument or contract to which it is party or by which it is

bound or of any judgment, decree, order, writ. The execution of and performance of the transactions contemplated by this Agreement and the Related Agreements, and compliance with their respective provisions by the Company, will not (a) conflict with or violate any provision of the Certificate of Incorporation or By-laws of the Company; (b) require on the part of the Company any filing with, or any permit, authorization, consent or approval of, any court, arbitrational tribunal, administrative agency or commission or other governmental or regulatory authority or agency (each of the foregoing is hereafter referred to as a "Governmental Entity"); (c) conflict with, result in a breach of, constitute (with or without due notice or lapse of time or both) a default under, result in the acceleration of, create in any party the right to accelerate, terminate, modify or cancel, or require any notice, consent or waiver under, any contract, lease, sublease, license, sublicense, franchise, permit, indenture, agreement or mortgage for borrowed money, instrument of indebtedness, or other arrangement to which the Company is a party or by which the Company is bound or to which its assets are subject; (d) result in the imposition of any mortgage, pledge, security interest, encumbrance, charge, or other lien (whether arising by contract or by operation of law) upon any assets of the Company; or (e) violate any order, writ, injunction, decree, statute, rule or regulation applicable to the Company or any of its properties or assets.

3.13 Litigation. There is no action, suit, proceeding or investigation pending or, to the Company's knowledge, currently threatened against the Company that questions the validity of this Agreement, the Related Agreements or the right of the Company to enter into any of such agreements, or to consummate the transactions contemplated hereby or thereby, or which might result, either individually or in the aggregate, in any material adverse change in the business, assets, properties, operations, prospects or financial condition of the Company, financially or otherwise, or any change in the current equity ownership of the Company, nor is the Company aware that there is any basis for any of the foregoing. The foregoing includes, without limitation, actions pending or threatened (or any basis therefor known to the Company) involving the prior employment of any of the Company's employees, their use in connection with the Company's business of any information or techniques allegedly proprietary to any of their former employers, or their obligations under any agreements with prior employers. The Company is not a party or subject to the provisions of any order, writ, injunction, judgment or decree of any court or government agency or instrumentality. There is no action, suit, proceeding or investigation by the Company currently pending or which the Company intends to initiate.

3.14 Tax Returns and Payments. The Company has timely filed all foreign, federal, state, county and local income, excise or franchise tax returns, real estate and personal property tax returns, sales and use tax returns and other tax returns and reports required to be filed by it and such returns and reports are true and correct in all material respects. All taxes shown to be due and payable on such returns, any assessments imposed, and to the Company's knowledge all other taxes due and payable by the Company on or before the Closing, have been paid or will be paid prior to the time they become delinquent. The Company has no knowledge of any liability of any tax to be imposed upon its properties or assets as of the date of this Agreement that is not adequately provided for in the Financial Statements. With regard to the income tax returns of the Company, the Company has not received notice of any audit or of any proposed deficiencies from any taxing authority, and no controversy with respect to taxes of any

type is pending or, to the knowledge of the Company, threatened. There are in effect no waivers of applicable statutes of limitations with respect to any taxes owed by the Company for any year. There is no tax lien (other than for current taxes not yet due and payable), whether imposed by any federal, state or other taxing authority, outstanding against the assets, properties or business of the Company. The Company has not elected pursuant to the Internal Revenue Code of 1986, as amended (the "Code") to be treated as an S corporation pursuant to Section 1362(a) of the Code or a collapsible corporation pursuant to Section 341(f) of the Code, nor has it made any other elections pursuant to the Code (other than elections that relate solely to methods of accounting, depreciation, or amortization) that would have a Material Adverse Effect.

- Employees. The Company has no collective bargaining agreements with any of its employees. There is no labor union organizing activity pending or, to the Company's knowledge, threatened with respect to the Company. To the Company's knowledge, no employee of the Company, nor any consultant with whom the Company has contracted, is in violation of any term of any employment contract, proprietary information agreement or any other agreement relating to the right of any such individual to be employed by, or to contract with, the Company because of the nature of the business to be conducted by the Company; and to the Company's knowledge the continued employment by the Company of its present employees, and the performance of the Company's contracts with its independent contractors, will not result in any such violation. The Company has not received any notice alleging that any such violation has occurred. No employee of the Company has been granted the right to continued employment by the Company or to any severance or other material compensation following termination of employment with the Company. The Company is not aware that any officer or key employee, or that any group of key employees, intends to terminate his, her or their employment with the Company, nor does the Company have a present intention to terminate the employment of any officer, key employee or group of key employees. The Company has complied in all material respects with all applicable laws relating to the employment of its personnel, including provisions relating to hours worked, wages, equal opportunity, collective bargaining and the payment of social security and other taxes.
- 3.16 Scientific Advisory Board. Each member of the Company's Scientific Advisory Board has executed a Consulting Agreement, substantially in the form attached hereto as **Exhibit I**.
- 3.17 Registration Rights. Except as required pursuant to the Investors' Rights Agreement, the Company is presently not under any obligation, and has not granted or agreed to grant any rights, to register (as defined in Section 1.1 of the Investors' Rights Agreement) any of the Company's presently outstanding securities or any of its securities that may hereafter be issued.
- 3.18 Compliance with Laws; Permits. The Company is not in violation of any applicable statute, rule, regulation, order or restriction of any domestic or foreign government or any instrumentality or agency thereof (including, without limitation, laws relating to the environment, ERISA and occupational health and safety) in respect of the conduct of its business or the ownership of its properties which violation would have a Material Adverse Effect. No governmental orders, permissions, consents, approvals or authorizations are required to be obtained and no registrations or declarations are required to be filed in connection with the

execution and delivery of this Agreement and the issuance of the Shares or the Conversion Shares, except such as have been duly and validly obtained or filed, or with respect to any filings that must be made after the Closing, as will be filed in a timely manner. The Company has all franchises, permits, licenses and any similar authorizations necessary for the conduct of its business as now being conducted by it, except for those franchises, permits, licenses or authorizations the lack of which could not have a Material Adverse Effect and which the Company believes it can obtain, without undue burden or expense.

- 3.19 Environment and Safety Laws. To its knowledge, the Company is not in violation of any applicable statute, law or regulation relating to the environment or occupational health and safety, and no material expenditures are required in order to comply with any such existing statute, law or regulation with respect to the operations of the Company as presently conducted. To the Company's knowledge, no Hazardous Materials (as defined below) are used or have been used, stored, or disposed of by the Company in violation of applicable law. For purposes of the preceding sentence, "Hazardous Materials" shall mean (a) materials which are listed or otherwise defined as "hazardous" or "toxic" under any applicable local, state, federal and/or foreign laws and regulations that govern the existence and/or remedy of contamination on property, the protection of the environment from contamination, the control of hazardous wastes, or other activities involving hazardous substances, including building materials, or (b) any petroleum products or nuclear materials.
- 3.20 Offering Valid. Assuming the accuracy of the representations and warranties of the Purchasers contained in Section 4.2 hereof, the offer, sale and issuance of the Shares and the Conversion Shares will be exempt from the registration requirements of the Securities Act of 1933, as amended (the "Securities Act"), and will have been registered or qualified (or are exempt from registration and qualification) under the registration, permit or qualification requirements of all applicable state securities laws. Neither the Company nor any agent on its behalf has solicited or will solicit any offers to sell or has offered to sell or will offer to sell all or any part of the Shares to any person or persons so as to bring the sale of such Shares by the Company within the registration provisions of the Securities Act.
- **3.21 Insurance.** The Company maintains valid policies of workers' compensation insurance and of insurance with respect to its properties and business of the kinds and in the amounts customarily maintained by companies engaged in the same or similar business and similarly situated, including, without limitation, insurance against loss, damage, fire, casualty, theft, general public liability and other risks.
- **3.22 Brokerage**. There are no claims for brokerage commissions, finders fees or similar compensation in connection with the transactions contemplated by this Agreement based on any arrangement or agreement made by or on behalf of the Company.
- 3.23 Disclosure. Neither this Agreement nor any exhibits hereto, nor any report, certificate, or instrument furnished to any of the Purchasers or their special counsel in connection with the transactions contemplated by this Agreement, when read together, contains any untrue statement of a material fact or omits to state a material fact necessary in order to make the statement contained herein or therein, in light of the circumstances under which they were made, not misleading. Each projection and budget furnished to the Purchasers by the Company

was prepared in good faith based on assumptions believed by the Company to be reasonable and represents the Company's good faith estimate of future results based on information available as of the respective dates of the presentations and the budget; provided that no representation is made as to whether the financial results reflected in such projections or budget will in fact be achieved.

- 3.24 ERISA. Except as set forth on the Schedule of Exceptions, the Company does not maintain any employee benefit plans (as defined in Section 3(3) of the Employee Retirement Income Security Act of 1974, as amended ("ERISA")). To the extent that the Company does maintain any such employee benefit plans, each plan complies in all material respects with (i) all applicable requirements of ERISA, and (ii) all applicable requirements of the Code.
- 3.25 Books and Records. The minute books of the Company contain complete and accurate records of all meetings and other corporate actions of its stockholders and its Board of Directors and committees thereof. The stock ledger of the Company is complete and reflects all issuances, transfers, repurchases and cancellations of shares of capital stock of the Company.
- 3.26 Qualified Small Business. The Company represents and warrants to the Purchasers that, to the best of its knowledge, the Company is a "qualified small business" within the meaning of Section 1202(d) of the Code, as of the date hereof and the Shares should qualify as "qualified small business stock" as defined in Section 1202(c) of the Code as of the date hereof. The Company further represents and warrants that, as of the date hereof, it meets the "active business requirement" of Section 1202(e) of the Code, and it has made no "significant redemptions" within the meaning of Section 1202(c)(3)(B) of the Code.
- **3.27 Real Property Holding Company.** The Company is not a real property holding company within the meaning of Section 897 of the Code.
- **3.28** Investment Company. The Company is not an "investment company" within the meaning of the Investment Company Act of 1940, as amended, and will not, as a result of the transactions contemplated hereby, become an "investment company".

#### 4. REPRESENTATIONS AND WARRANTIES OF THE PURCHASERS.

Each Purchaser severally and not jointly hereby represents and warrants to the Company as follows (such representations and warranties do not lessen or obviate the representations and warranties of the Company set forth in this Agreement):

4.1 Requisite Power and Authority. Purchaser has all necessary power and authority under all applicable provisions of law to execute and deliver this Agreement and the Related Agreements and to carry out their respective provisions. All action on such Purchaser's part required for the lawful execution and delivery of this Agreement and the Related Agreements have been or will be effectively taken prior to the Closing. Upon their execution and delivery, this Agreement and the Related Agreements will be valid and binding obligations of such Purchaser, enforceable in accordance with their respective terms, except (a) as limited by applicable bankruptcy, insolvency, reorganization, moratorium or other laws of general application affecting enforcement of creditors' rights, (b) general principles of equity that restrict

the availability of equitable remedies, and (c) to the extent that the enforceability of the indemnification provisions of Section 2.9 of the Investors' Rights Agreement may be limited by applicable laws.

- **4.2 Investment Representations.** Purchaser understands that neither the Shares nor the Conversion Shares have been registered under the Securities Act. Purchaser also understands that the Shares are being offered and sold pursuant to an exemption from registration contained in the Securities Act based in part upon such Purchaser's representations contained in this Agreement. Purchaser hereby represents and warrants as follows:
- (a) Purchaser Bears Economic Risk. Purchaser has substantial experience in evaluating and investing in private placement transactions of securities in companies similar to the Company so that he, she or it is capable of evaluating the merits and risks of the investment in the Company and has the capacity to protect his, her or its own interests. Purchaser must bear the economic risk of this investment indefinitely unless the Shares (or the Conversion Shares) are registered pursuant to the Securities Act, or an exemption from registration is available. Purchaser understands that the Company has no present intention of registering the Shares, the Conversion Shares or any shares of its Common Stock. Purchaser also understands that there is no assurance that any exemption from registration under the Securities Act will be available and that, even if available, such exemption may not allow Purchaser to transfer all or any portion of the Shares or the Conversion Shares under the circumstances, in the amounts or at the times Purchaser might propose.
- **(b)** Acquisition for Own Account. Purchaser is acquiring the Shares and the Conversion Shares for Purchaser's own account for investment only, and not with a view towards their distribution.
- (c) Purchaser Can Protect Its Interest. Purchaser has, by reason of its, or of its management's, business or financial experience, the capacity to protect his, her or its own interests in connection with the transactions contemplated in this Agreement and the Related Agreements. Further, Purchaser is aware of no publication of any advertisement in connection with the transactions contemplated in this Agreement.
- (d) Accredited Investor. Purchaser is an accredited investor within the meaning of Regulation D under the Securities Act.
- **(e)** Company Information. Purchaser has had an opportunity to discuss the Company's business, management and financial affairs with directors, officers and management of the Company and has had the opportunity to review the Company's operations and facilities. Purchaser has also had the opportunity to ask questions of and receive answers from, the Company and its management regarding the terms and conditions of this investment.
- (f) Rule 144. Purchaser acknowledges and agrees that the Shares, and, if issued, the Conversion Shares, must be held indefinitely unless they are subsequently registered under the Securities Act or an exemption from such registration is available.

- (g) Residence. If the Purchaser is an individual, then the Purchaser resides in the state or province identified in the address of the Purchaser set forth on Exhibit A; if the Purchaser is a partnership, corporation, limited liability company or other entity, then the office or offices of the Purchaser in which its investment decision was made is located at the address or addresses of such Purchaser as set forth on Exhibit A.
- **4.3 Transfer Restrictions.** Each Purchaser acknowledges and agrees that the Shares and, if issued, the Conversion Shares are subject to restrictions on transfer as set forth in the Investors' Rights Agreement.
- **4.4 Brokerage**. There are no claims for brokerage commissions, finders fees or similar compensation in connection with the transactions contemplated by this Agreement based on any arrangement or agreement made by or on behalf of the Purchaser.

#### 5. CONDITIONS TO CLOSING.

- 5.1 Conditions to Purchasers' Obligations at Each Closing. Purchasers' obligations to purchase the Shares at the Initial Closing and at any Additional Closing are subject to the satisfaction or waiver, at or prior to such Closing Date, of the following conditions:
- (a) Representations and Warranties True. The representations and warranties made by the Company in Section 3 hereof shall be true and correct in all material respects (except for those representations and warranties that are qualified as to materiality, Material Adverse Effect or any similar materiality qualifier which shall be true and correct in all respects) on and as of the Initial Closing Date with the same force and effect as if they had been made on and as of such Closing Date, except for the representations and warranties that are made as of a certain date which shall be true and correct as of that certain date.
- **(b) Performance of Obligations.** The Company shall have performed and complied with all agreements, obligations and conditions contained herein required to be performed or complied with by it on or prior to such Closing.
- (c) Consents, Permits, and Waivers. The Company shall have obtained any and all consents, permits and waivers necessary or appropriate for consummation of the transactions contemplated by this Agreement and the Related Agreements (except for such as may be properly obtained subsequent to such Closing).
- (d) Filing of Restated Charter. The Restated Charter shall have been filed with the Secretary of State of the State of Delaware and shall continue to be in full force and effect as of such Closing Date.
- **(e)** Corporate Documents. The Company shall have delivered to Purchasers or their counsel, copies of all corporate documents of the Company as Purchasers shall reasonably request.

- **(f)** Reservation of Conversion Shares. The Conversion Shares issuable upon conversion of the Shares shall have been duly authorized and reserved for issuance upon such conversion.
- (g) Certificates and Documents. Prior to the Initial Closing, and at each Additional Closing upon the request of an Additional Purchaser, the Company shall have delivered to each of the Purchasers:
- (i) Certificates, dated no more than five days prior to the date of such Closing, as to the corporate good standing of the Company issued by the Secretary of State of Delaware and the Secretary of the Commonwealth of Massachusetts;
- (ii) Compliance Certificate executed by the Chief Executive Officer of the Company, dated as of the date of such Closing, certifying as to the fulfillment of the conditions specified in Sections 5.1(a) through 5.1(f) of this Agreement.
- (iii) Certificate of the Secretary of the Company, dated as of the date of such Closing certifying as to (A) the incumbency of the Company's principal officers, (B) a copy of the Certificate of Incorporation, certified by the Secretary of State of the State of Delaware, as in effect immediately prior to such Closing Date, (C) a copy of the By-laws of the Company, as in effect on and as of such Closing Date, and (D) a copy of the resolutions of the Board of Directors and the stockholders of the Company, authorizing and approving all matters in connection with this Agreement, the Related Agreements and the transactions contemplated hereby and thereby.
- **(h) Investors' Rights Agreement.** A Seventh Amended and Restated Investors' Rights Agreement substantially in the form attached hereto as **Exhibit C** shall have been executed and delivered by the Company and the parties thereto.
- (i) Voting Agreement. A Fourth Amended and Restated Voting Agreement substantially in the form attached hereto as **Exhibit D** shall have been executed and delivered by the Company and the parties thereto.
- (j) Proceedings and Documents. All corporate and other proceedings in connection with the transactions contemplated at the Initial Closing hereby and all documents and instruments incident to such transactions shall be reasonably satisfactory in substance and form to the Purchasers and their special counsel, and the Purchasers and their special counsel shall have received all such counterpart originals or certified or other copies of such documents as they may reasonably request.
- (k) Legal Opinion. The Purchasers shall have received from Company counsel an opinion addressed to them, dated as of the Initial Closing Date, in substantially the form attached hereto as  $Exhibit\ F$ .
- (l) Minimum Investment. The Initial Purchasers identified on Exhibit A shall purchase at least \$25,000,000 in shares of Series G Stock at the Initial Closing.

- 5.2 Conditions to Obligations of the Company. The Company's obligation to issue and sell the Shares at the Initial Closing and at any Additional Closing is subject to the satisfaction, on or prior to such Closing, of the following conditions:
- (a) Representations and Warranties True. The representations and warranties made by such Purchasers in Section 4 hereof shall be true and correct on and as of such Closing, with the same force and effect as if they had been made on and as of such Closing Date.
- **(b) Performance of Obligations.** Such Purchasers shall have performed and complied with all agreements, obligations and conditions contained herein required to be performed or complied with by such Purchasers on or prior to such Closing.
- (c) Investors' Rights Agreement. A Seventh Amended and Restated Investors' Rights Agreement substantially in the form attached hereto as Exhibit C shall have been executed and delivered by the Purchasers.
- (d) Voting Agreement. A Fourth Amended and Restated Voting Agreement substantially in the form attached hereto as **Exhibit D** shall have been executed and delivered by the Investors named therein.
- (e) Consents, Permits, and Waivers. The Company shall have obtained any and all consents, permits and waivers necessary or appropriate for consummation of the transactions contemplated by this Agreement and the Related Agreements (except for such as may be properly obtained subsequent to the Closing).

#### 6. MISCELLANEOUS.

- Agreement is contrary to any mandatory provision of the Delaware General Corporation Law (in which case such mandatory statutory provision shall apply), this Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts and the laws of the United States applicable therein (without giving effect to any choice or conflict of laws provision or rule that would cause the application of the laws of any other jurisdiction) and shall be treated in all respects as a Massachusetts contract. Any action, suit or proceeding arising out of or relating to this Agreement shall be brought in the courts of the Commonwealth of Massachusetts and each of the parties hereto hereby irrevocably submits (i) in the case of a suit or proceeding to which the Company is a party, to the exclusive jurisdiction of such courts and (ii) in the case of a suit or proceeding to which the Company is not a party, to the non-exclusive jurisdiction of such courts.
- 6.2 Survival. The representations, warranties, covenants and agreements made herein shall survive any investigation made by any Purchaser and the execution and delivery of this Agreement and the closing of the transactions contemplated hereby for a period of three (3) years following the Initial Closing. All statements as to factual matters contained in any certificate or other instrument delivered by or on behalf of the Company pursuant hereto in

connection with the transactions contemplated hereby shall be deemed to be representations and warranties by the Company hereunder solely as of the date of such certificate or instrument.

- 6.3 Successors and Assigns. Except as otherwise expressly provided herein, the provisions hereof shall inure to the benefit of, and be binding upon, the successors, assigns, heirs, executors and administrators of the parties hereto and shall inure to the benefit of and be enforceable by each person who shall be a holder of the Shares from time to time. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and assigns any rights, remedies, obligations, or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement.
- 6.4 Entire Agreement. This Agreement, the Exhibits and Schedules hereto, the Related Agreements and the other documents delivered pursuant hereto or thereto constitute the full and entire understanding and agreement between the parties with regard to the subjects hereof and supersede all prior agreements and understandings among the parties, written or oral, with respect thereto. No party shall be liable or bound to any other in any manner by any representations, warranties, covenants and agreements except as specifically set forth herein and therein.
- 6.5 Severability. In case any provision of this Agreement shall be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.

#### 6.6 Amendment and Waiver.

- (a) This Agreement may be amended or modified only upon the written consent of the Company and holders of at least a majority of the then outstanding Shares (treated as if converted and including any Conversion Shares into which the Shares have been converted that have not been sold to the public).
- (b) The obligations of the Company and the rights of the holders of the Shares and the Conversion Shares under this Agreement may be waived (either generally or in a particular instance and either retroactively or prospectively) only with the written consent of the holders of at least a majority of the then outstanding Shares (treated as if converted and including any Conversion Shares into which the Shares have been converted that have not been sold to the public); provided, however, that no condition set forth in Section 5 may be waived with respect to any Purchaser who does not consent thereto. No waivers of or exceptions to any term, condition or provision of this Agreement, in any one or more instances, shall be deemed to be, or construed as, a further or continuing waiver of any such term, condition or provision.
- 6.7 Delays or Omissions. It is agreed that no delay or omission to exercise any right, power or remedy accruing to any party, upon any breach, default or noncompliance by another party under this Agreement, the Related Agreements or the Restated Charter, shall impair any such right, power or remedy, nor shall it be construed to be a waiver of any such breach, default or noncompliance, or any acquiescence therein, or of or in any similar breach, default or noncompliance thereafter occurring. It is further agreed that any waiver, permit, consent or approval of any kind or character on any Purchaser's part of any breach, default or

noncompliance under this Agreement, the Related Agreements or under the Restated Charter or any waiver on such party's part of any provisions or conditions of this Agreement, the Related Agreements or the Restated Charter must be in writing and shall be effective only to the extent specifically set forth in such writing. All remedies, either under this Agreement, the Related Agreements and the Restated Charter, by law, or otherwise afforded to any party, shall be cumulative and not alternative.

- 6.8 Notices. All notices required or permitted hereunder shall be in writing and shall be deemed effectively given: (a) upon personal delivery to the party to be notified, (b) when sent by confirmed telex or facsimile if sent during normal business hours of the recipient, if not, then on the next business day, (c) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (d) one (1) day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt. All communications shall be sent to the party at such party's address as set forth below or as subsequently modified by ten (10) days advance written notice to the other parties hereto, as follows:
  - (i) if to the Company, to:

Microbia, Inc.
320 Bent Street
Cambridge, MA 02141
Telephone: (617) 621-7722
Facsimile: (617) 494-0908

or at such other address or addresses as may have been furnished in writing by the Company to the Purchasers,

- (ii) if to any Purchaser, at such Purchaser's respective address set forth on Exhibit A.
- **6.9 Expenses.** Each party shall pay all costs and expenses that it incurs with respect to the negotiation, execution, delivery and performance of this Agreement; *provided*, *however*, that the Company shall, at the Initial Closing, reimburse the reasonable fees of and expenses of one (1) counsel for the Purchasers, not to exceed \$25,000.
- **6.10** Attorneys' Fees. In the event that any suit or action is instituted to enforce any provision in this Agreement, the prevailing party in such dispute shall be entitled to recover from the losing party all fees, costs and expenses of enforcing any right of such prevailing party under or with respect to this Agreement, including without limitation, such reasonable fees and expenses of attorneys and accountants, which shall include, without limitation, all fees, costs and expenses of appeals.
- 6.11 Titles and Subtitles. The titles of the sections and subsections of this Agreement are for convenience of reference only and are not to be considered in construing this Agreement.

- **6.12** Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together shall constitute one instrument. This Agreement may be executed by facsimile signatures.
- 6.13 Exculpation Among Purchasers. Each Purchaser acknowledges that it is not relying upon any person, firm, or corporation, other than the Company, in making its investment or decision to invest in the Company. Each Purchaser agrees that no Purchaser nor the respective controlling persons, officers, directors, partners, agents, or employees of any Purchaser shall be liable to any other Purchaser for any action heretofore or hereafter taken or omitted to be taken by any of them in connection with the Shares and Conversion Shares.

- Confidentiality. Each party hereto agrees that, except with the prior written consent of the other party, it shall at all times keep confidential and not divulge, furnish or make accessible to anyone any confidential information, knowledge or data concerning or relating to the business or financial affairs of the other parties to which such party has been or shall become privy by reason of this Agreement or the Related Agreements, discussions or negotiations relating to this Agreement or the Related Agreements, the performance of its obligations hereunder or the ownership of the Shares purchased hereunder; provided, however, that a Purchaser may disclose confidential information, knowledge or data concerning or relating to the business or financial affairs of the Company (i) to its attorneys, accountants and consultants, to the extent necessary to obtain their services in connection with monitoring its investment in the Company, provided that such attorney, accountant or consultant is legally obligated not to use or disclose any such information, knowledge or data or (ii) as may otherwise be required by law, provided that the Purchaser takes reasonable steps to minimize the extent of any such required disclosure. The provisions of this Section 6.14 shall be in addition to, and not in substitution for, the provisions of any separate nondisclosure agreement executed by the parties hereto.
- **6.15 Pronouns.** All pronouns contained herein, and any variations thereof, shall be deemed to refer to the masculine, feminine or neutral, singular or plural, as the identity of the parties hereto may require.

In W	ITNESS	WHEREOF,	the parties	hereto	ha	ve e	execut	ed t	he SE	RIE	es G	CON	VERTIBLE
PREFERRED	STOCK	<b>PURCHASE</b>	AGREEME	ent as	of	the	date	set	forth	in	the	first	paragraph
hereof.													

Cor	npany:
MI	CROBIA, INC.
_	
By:	
	Peter M. Hecht
	Chief Executive Officer
	Unier Executive Officer

# MICROBIA, INC. PURCHASER SIGNATURE PAGE (for Designated Offering Investors)

#### **Initial Closing**

By his, her or its execution and delivery of this signature page, the undersigned Purchaser hereby joins in and agrees to be bound by the terms and conditions of the:

- (i) Series G Convertible Preferred Stock Purchase Agreement dated as of the date set forth in the first paragraph thereof (the "Purchase Agreement") by and among Microbia, Inc. (the "Company") and the Purchasers listed on Exhibit A thereto, as to the number of shares of Series G Stock set forth below;
- (ii) Seventh Amended and Restated Investors' Rights Agreement dated as of the date set forth in the first paragraph thereof, by and among the Company and the Investors listed on **Exhibit A** thereto (the "Investors' Rights Agreement"), as an "Investor" thereunder;
- (iii) Fourth Amended and Restated Voting Agreement dated as of the date set forth in the first paragraph thereof, by and among the Company and the Stockholders listed on **Exhibit A** thereto (the "Voting Agreement"), as a "Stockholder" thereunder; and authorizes this signature page to be attached to the Purchase Agreement, the Investors' Rights Agreement and the Voting Agreement, or counterparts thereof.

ii

Print Name of Purchaser	
By:	
Name:	
Title:	
Record Address:	
Telephone No.:	
Facsimile No.:	
E-mail Address:	,
Number of Shares of	<u>-</u>
Series G Stock:	

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#### MICROBIA, INC.

# PURCHASER SIGNATURE PAGE (for Non-Designated Offering Investors)

#### **Initial Closing**

By his, her or its execution and delivery of this signature page, the undersigned Purchaser hereby joins in and agrees to be bound by the terms and conditions of the:

- (i) Series G Convertible Preferred Stock Purchase Agreement dated as of the date set forth in the first paragraph thereof (the "Purchase Agreement") by and among Microbia, Inc. (the "Company") and the Purchasers listed on Exhibit A thereto, as to the number of shares of Series G Stock set forth below;
- (ii) Seventh Amended and Restated Investors' Rights Agreement dated as of the date set forth in the first paragraph thereof, by and among the Company and the Investors listed on Exhibit A thereto (the "Investors' Rights Agreement"), as an "Investor" thereunder; and
- (iii) Fourth Amended and Restated Voting Agreement dated as of the date set forth in the first paragraph thereof, by and among the Company and the Stockholders listed on **Exhibit A** thereto (the "Voting Agreement"), as a "Stockholder" thereunder; and authorizes this signature page to be attached to the Purchase Agreement, the Investors' Rights Agreement and the Voting Agreement, or counterparts thereof.

Print Name of Purchaser	
By:	
Name:	
Title:	
Record Address:	
Telephone No.:	
Facsimile No.:	
E-mail Address:	
Number of Shares of	
Series G Stock:	

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# MICROBIA, INC. PURCHASER SIGNATURE PAGE (for Designated Offering Investors) Additional Closing

By his, her or its execution and delivery of this signature page, the undersigned Purchaser hereby joins in and agrees to be bound by the terms and conditions of the:

- (i) Series G Convertible Preferred Stock Purchase Agreement dated as of [•] (the "Purchase Agreement") by and among Microbia, Inc. (the "Company") and the Purchasers listed on Part II of Exhibit A thereto, as to the number of shares of Series G Stock set forth below;
- (ii) Seventh Amended and Restated Investors' Rights Agreement dated as of [•], by and among the Company and the Investors listed on **Exhibit A** thereto (the "Investors' Rights Agreement"), as an "Investor" thereunder; and
- (iii) Fourth Amended and Restated Voting Agreement dated as of [•], by and among the Company and the Stockholders listed on **Exhibit A** thereto (the "Voting Agreement"), as an "Stockholder" thereunder; and

authorizes this signature page to be attached to the Purchase Agreement, the Investors' Rights Agreement and the Voting Agreement, or counterparts thereof.

Print Name of Purchaser	
By:	
Name:	
Title:	
Record Address:	
Telephone No.:	
Facsimile No.:	
E-mail Address:	
Number of Shares of	
Series G Stock:	

# MICROBIA, INC. PURCHASER SIGNATURE PAGE (for Non-Designated Offering Investors) Additional Closing

By his, her or its execution and delivery of this signature page, the undersigned Purchaser hereby joins in and agrees to be bound by the terms and conditions of the:

- (i) Series G Convertible Preferred Stock Purchase Agreement dated as of [•] (the "Purchase Agreement") by and among Microbia, Inc. (the "Company") and the Purchasers listed on Exhibit A thereto, as to the number of shares of Series G Stock set forth below;
- (ii) Seventh Amended and Restated Investors' Rights Agreement dated as of [•], by and among the Company and the Investors listed on **Exhibit A** thereto (the "Investors' Rights Agreement"), as an "Investor" thereunder;
- (iii) Fourth Amended and Restated Voting Agreement dated as of [•], by and among the Company and the Stockholders listed on **Exhibit A** thereto (the "Voting Agreement"), as a "Stockholder" thereunder; and

authorizes this signature page to be attached to the Purchase Agreement, the Investors' Rights Agreement and the Voting Agreement, or counterparts thereof.

Print Name of Purchaser	
Ву:	
Name:	
Title:	
Record Address:	
Telephone No.:	
Facsimile No.:	· · · · · · · · · · · · · · · · · · ·
E-mail Address:	
Number of Shares of	
Series G Stock:	

SCHEDULE 5.2.2(ii)

**PIPE Term Sheet** 

#### MICROBIA, INC.

# FOREST LABORATORIES, INC. \$25M PRIVATE PLACEMENT TERM SHEET

Issuer: Microbia, Inc., a Delaware corporation (the "Company").

Purchaser: Forest Laboratories, Inc., a Delaware corporation (the "Purchaser").

Type of Securities: 2,083,334 shares of the Company's common stock, at \$12.00 per share, as may be

adjusted pursuant to Section 5.2.2 of the Collaboration Agreement dated September 12, 2007, by and between the Company and the Purchaser, the "Collaboration

Agreement").

Amount of Offering:

\$25 million

Closing Date: The date described in Section 5.2.2 of the Collaboration Agreement.

Use of Proceeds: The Company will use the proceeds it receives from the sale of the Common Stock

for general corporate purposes.

Registration Rights:

The Company shall file a shelf registration statement for the shares of Common Stock on Form S-3 or such other form as the Company is eligible to use (the "Registration Statement"). Such Registration Statement shall be filed as soon as practicable but in any event within 30 days of the Closing Date. The Company shall use commercially reasonable efforts to cause the Registration Statement to be declared effective by the Securities and Exchange Commission (the "SEC") as soon as practicable and, in any event, within 90 days after the Closing Date, or, in the event of a review of the Registration Statement by the SEC, within 120 days after the Closing Date. Should the Registration Statement not be filed within 30 days of the Closing Date or declared effective within the 90-day or 120-day period, as applicable, following the Closing Date, the Company shall pay each Purchaser liquidated damages of 1.25% per month for a maximum of 12 months, in cash, based on the principal amount invested by each such Purchaser. Such Registration Statement shall remain effective until the earlier of (i) the date all securities registered have been sold or (ii) the date when all shares held by the Purchaser can be sold under Rule 144 in a 90 day period. The Registration Statement will be effected pursuant to an agreement with registration rights terms substantially in the form of those in the form of Investors' Rights

Agreement attached to the form of Stock Purchase Agreement.

Confidentiality: This document and the documents associated with the transaction (and the subject

matter hereof and thereof) will not be disclosed to any persons other than the Company, the Purchaser and their respective advisors without the prior written consent of the non-disclosing parties, except as may be required by law or regulation.

Nature of Document:

The closing of the transactions contemplated by this Term Sheet will be subject to a number of standard conditions. Accordingly, except as provided above under the caption "Confidentiality," this Term Sheet does not constitute a legally binding

obligation of the parties hereto.

# SCHEDULE 7.2(a)

### **Microbia Patent Rights**

The following are those patent applications and patents Controlled by Microbia which, Microbia, as of the Effective Date, has identified as potentially being useful in connection with the Product in the Field and Territory.

country	Application Serial Number	Filing Date	Status		
PCT	PCT/US2004/002390	01/28/04	NAT PHASE		
US	10/766,735	01/28/04	non-final office action (05/01/07)		
CA	2514507	01/28/04	PENDING		
MX	PA/A/2005/008097	01/28/04	PENDING		
US	10/796,719	03/09/04	notice of allowance (08/22/07)		
US	10/845,895	05/14/04	non-final office action (07/13/07)		
PCT	PCT/US2004/018751	06/14/04	NAT PHASE		
US	10/868,744	06/14/04	non-final office action (03/22/07)		
CA	2529307	06/14/04	PENDING		
US	10/899,806	07/27/04	non-final office action (07/13/07)		
PCT	PCT/US2005/002941	01/31/05	PUBLISHED		
US	10/587,450	01/31/05	no substantive office actions		
US	11/054,071	02/08/05	no substantive office actions		
US	11/054,072	02/08/05	non-final office action (07/5/07)		
PCT	PCT/US2005/007752	03/08/05	PUBLISHED		
CA	2558050	03/08/05	PENDING		
MX	PA/A/2006/010205	03/08/05	PENDING		
PCT	PCT/US2006/004768	02/08/06	NAT PHASE		

PCT	PCT/US2006/009696	03/17/06	PUBLISHED		
PCT	PCT/US2006/032719	08/21/06	PUBLISHED		
[CA	not yet assigned	02/08/07	PENDING]		
PCT	PCT/US2007/062820	02/26/07	PENDING		
US	PCT/US2007/062815	02/26/07	PENDING		
US	60/891,626	02/26/07	PENDING		
US	60/916,257	05/04/07	PENDING		
US	60/941,255	05/31/07	PENDING		
PCT	PCT/US2007/72223	06/27/07	PENDING		

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# SCHEDULE 7.2(c)

Microbia Patent Rights developed with Government Funding

None

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# SCHEDULE 7.2(d)

Microbia Agreements with Third Parties Relating to Microbia Patent Rights

None

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SCHEDULE 7.3(a)

**Forest Patent Rights** 

None

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# SCHEDULE 7.3(c)

Forest Patent Rights developed with Government Funding

None

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## Schedule 7.3(e)

### **Forest Products in Development**

**Dexloxiglumide** 

Milnacipran (under consideration).]

#### **AMENDMENT NO. 1 TO MASTER COLLABORATION AGREEMENT**

This AMENDMENT NO. 1 TO MASTER COLLABORATION AGREEMENT (the "<u>Amendment</u>") is entered into on this 3rd day of November, 2009 (the "<u>Amendment Effective Date</u>"), by and among Ironwood Pharmaceuticals, a Delaware corporation (formerly Microbia, Inc.) ("<u>Ironwood</u>") and Forest Laboratories, Inc. ("<u>Forest</u>"). Ironwood and Forest may each be referred to herein individually as a "<u>Party</u>" and collectively as the "<u>Parties</u>."

#### **BACKGROUND**

Ironwood and Forest entered into a Master Collaboration Agreement dated as of September 12, 2007 (the "Agreement").

Ironwood and Forest now desire to make certain clarifying changes to the Agreement in order to better reflect the intent of the Parties.

#### **AGREEMENT**

NOW THEREFORE, in consideration of the mutual promises and covenants set forth below and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

#### I. LICENSE AMENDMENT.

- A. Section 2.2(i) of the Agreement is hereby deleted in its entirety and replaced with the following:
  - "(i) under Microbia's interest in the Microbia Technology and the Joint Technology to Develop pursuant to the Development Plan and Manufacture the Product anywhere in the world solely for purposes of Commercialization in the Field in the Territory and to Commercialize the Product in the Field in the Territory, and"
- B. Section 2.3(ii)(x) of the Agreement is hereby deleted in its entirety and replaced with the following:
  - "(x) under Forest's interest in the Forest Technology and the Joint Technology to develop, manufacture and commercialize the Collaboration Compound and Product in the Field outside of the Territory and to develop (subject to the proviso in the final sentence of Section 2.2 above) and manufacture the Product in the Territory for purposes of commercialization in the Field outside the Territory and"

#### II. GENERAL.

- A. Except as amended by this Amendment, the Agreement shall remain in full force and effect in accordance with the terms thereof. Amendments made pursuant to this Amendment shall be effective as of the Effective Date.
- B. This Amendment may be executed in any number of counterparts, each of which shall be deemed an original and all of which taken together shall be deemed to constitute one and the same instrument. An executed signature page of this Amendment delivered by facsimile transmission shall be as effective as an original executed signature page.

[The remainder of this page has been intentionally left blank.]

IN WITNESS WHEREOF, duly authorized representatives of the Parties have duly executed this Amendment to be effective as of the Effective Date.

FOREST LABORATORIES, INC. IRONWOOD PHARMACEUTICALS, INC.

By: /s/ David Solomon By: /s/ James O'Mara

Name: David Solomon Name: James O'Mara Title: Vice President Title: Vice President