

**UNITED STATES BANKRUPTCY COURT  
DISTRICT OF DELAWARE**

In re:	)	Chapter 11
	)	
MIDDLEBROOK PHARMACEUTICALS, INC., <sup>1</sup>	)	Case No. 10-11485 (MFW)
	)	
Debtor.	)	Hearing Date: September 30, 2010 at 2:00 p.m. (ET) Resp. Deadline: September 23, 2010 at 4:00 p.m. (ET)

**DEBTOR'S OBJECTION TO PROOF OF CLAIM NO. 59  
FILED BY PAR PHARMACEUTICAL INC.**

MiddleBrook Pharmaceuticals, Inc., the above-captioned debtor and debtor in possession (the “**Debtor**”) hereby files this objection (the “**Claim Objection**”) to Proof of Claim No. 59 (the “**POC**”) filed by Par Pharmaceutical, Inc. (“**Par**”) on or about August 18, 2010 in the amount of \$11,625,000 (the “**Claim**”). As set forth more fully below, the Debtor seeks entry of an Order pursuant to Rule 3007 of the Federal Rules of Bankruptcy Procedure (the “**Bankruptcy Rules**”) and Section 502 of Title 11 of the United States Code (the “**Bankruptcy Code**”) disallowing the Claim in full and expunging the POC. In support of the Objection, the Debtor respectfully represents as follows:

**JURISDICTION AND VENUE**

1. The Court has jurisdiction over this Objection pursuant to 28 U.S.C. §§ 157 and 1334. Venue of this bankruptcy case and the Objection in this district is proper pursuant to 28 U.S.C. §§ 1408 and 1409. This matter is a core proceeding pursuant to 28 U.S.C. § 157(b)(2). The statutory predicates for the relief requested herein are Sections 502(b) and 1107 of the Bankruptcy Code and Bankruptcy Rules 3003(c) and 3007.

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<sup>1</sup> The last four digits of the Debtor’s taxpayer identification number are 8264. The Debtor’s mailing address is 7 Village Circle, Suite 100, Westlake, Texas 76262.



## BACKGROUND

### A. General Background of the Case

1. On April 30, 2010 (the “**Petition Date**”), the Debtor commenced a voluntary case (the “**Bankruptcy Case**”) under Chapter 11 of the Bankruptcy Code. Sections 1107(a) and 1108 of the Bankruptcy Code authorize the Debtor to operate its business and manage its assets as a debtor in possession. No party in interest has requested the appointment of a trustee or examiner.

2. On May 11, 2010, the United States Trustee for the District of Delaware (the “**United States Trustee**”) appointed an official committee of unsecured creditors (the “**Creditors’ Committee**”) in the Bankruptcy Case under Section 1102 of the Bankruptcy Code. [Docket No. 42].

3. On June 24, 2010, the United States Trustee appointed an official committee of equity security holders (the “**Equity Committee**”) in the Bankruptcy Case. [Docket No. 154].

4. On July 28, 2010, the Court entered an order (the “**Sale Order**”) approving the sale (“**Sale**”) of substantially all of the Debtor’s assets to Victory Pharma Inc. (“**Victory**”).

5. The Sale to Victory closed on July 30, 2010 (the “**Closing Date**”).

6. Following the Closing Date, the Debtor began winding down its operations.

7. On June 11, 2010, the Debtor filed a motion seeking authority to set various dates by which entities must file proofs of claim on account of any prepetition claims that they may assert against the Debtor or be forever barred from asserting such claim (the “**Bar Date Motion**”). [Docket No. 141].

8. On July 6, 2010, the Court granted the Bar Date Motion. [Docket No. 176].

9. On July 8, 2010, the Debtor filed and served a notice setting the following bar dates for the various claims specified below:

- i. general, unsecured claims - August 27, 2010 (the “**General Claims Bar Date**”);
- ii. claims by governmental units - October 31, 2010 (the “**Governmental Unit Bar Date**”);
- iii. holders of claims whose claims had been affected by an amendment to the Debtor’s schedules of assets and liabilities - 30 days from the day which such notice was given (the “**Amended Schedule Bar Date**”); and
- iv. holders of claims resulting from the rejection of an executory contract or unexpired lease - the later of (a) 30 days after the entry of the order authorizing rejection of such executory contract or unexpired lease or (b) the General Claims Bar Date (the “**Rejection Bar Date**”).

[Docket No. 183].

**B. Factual Background Specific to the Request for Relief**

10. On or about August 18, 2010, Par filed the POC asserting an unsecured claim against the Debtor in an amount not less than \$11,625,000.

11. In the POC, Par asserts that it has a claim against the Debtor on account of that certain Development and Commercialization Agreement between Par and Advancis Pharmaceutical Corporation, the former name of the Debtor, entered into as of May 28, 2004 and amended as of December 14, 2004 (attached hereto as Exhibits A and B; as amended, the “**Development Agreement**”). The alleged basis for the \$11,625,000 Claim is Section 4.2.2.3 of the Development Agreement, which states:

In the event that Par rightfully terminates this Agreement in accordance with the provisions of Section 4.2.2.2, then (i) no Development Funding Gap amounts shall be due or payable; and (ii) if such termination occurs after Par has paid to [MiddleBrook] in cash at least \$20,000,000 in Development Costs and [MiddleBrook] successfully commercializes the Products then [MiddleBrook] will reimburse Par for one-half of such amount (the “**Section 4.2.2.3 Amount**”) following the successful commercialization of the Products by making quarterly payments to Par equal to 15% of [MiddleBrook’s] net profits on sales of the Products in such quarter until [MiddleBrook] has refunded to Par the Section 4.2.2.3 Amount.

Development Agreement, § 4.2.2.3

12. In the POC, Par states that because it paid the Debtor \$23,250,000 in “Development Costs” as required by the Development Agreement and the Debtor commercialized MOXATAG, the Adult Product (described below), Par has a claim against the Debtor in the amount of \$11,625,000 (one half of \$23,250,000) pursuant to Section 4.2.2.3 of the Development Agreement. POC ¶ 3.

### **RELIEF REQUESTED**

13. By this Objection, the Debtor seeks entry of an order, pursuant to Bankruptcy Rule 3007 and Section 502 of the Bankruptcy Code, disallowing the Claim in full and expunging the POC.

### **BASIS FOR RELIEF**

14. The Debtor submits that Par has no claim, as that term is defined under the Bankruptcy Code, against the Debtor’s estate because Par has no right of payment pursuant to the express and unambiguous terms of the Development Agreement.

15. The Development Agreement must be interpreted in accordance with Delaware law. See Development Agreement § 18.3 (stating that the Development Agreement is “governed by and interpreted in accordance with the internal laws of the State of Delaware”). Under Delaware law, “When the language of a[] ... contract is clear and unequivocal, a party will be bound by its plain meaning because creating an ambiguity where none exists could, in effect, create a new contract with rights, liabilities and duties to which the parties had not assented.” Rhone-Poulenc Basic Chemicals Co. v. American Motorists Ins. Co., 616 A.2d 1192, 1196 (Del. 1992) (internal quotations omitted).

16. As discussed further below, under the clear and unequivocal terms of the Development Agreement, Par has no claim against the Debtor because, among other reasons,

(i) Par did not “rightfully terminate” the Development Agreement pursuant to and in accordance with the clear and unambiguous provisions of Section 4.2.2.2; (ii) Par did not pay at least \$20,000,000 in cash to the Debtor *before* it terminated the Development Agreement; (iii) the Debtor has not successfully commercialized the “*Products*” (as such term is defined in the Development Agreement) as set forth in Section 4.2.2.3; (iv) there have been no “net profits” from the sales of the single product that the Debtor did develop and commercialize; and (v) the single product developed and commercialized by the Debtor has not been “successfully” commercialized as required by Section 4.2.2.3.

**A. The Claim is Invalid Because Par Did Not Terminate the Development Agreement Pursuant to the Requirements of Section 4.2.2.2 of the Development Agreement**

17. There is no basis for the asserted Claim because Par did not terminate the Development Agreement pursuant to the clear and unambiguous provisions of Section 4.2.2.2 of the Development Agreement. Section 4.2.2.3 of the Development Agreement unequivocally states that the Section 4.2.2.3 Amount becomes due and payable to Par only in the event that Par “rightfully terminates [the Development Agreement] in accordance with the provisions of Section 4.2.2.2 [of the Development Agreement].” Development Agreement § 4.2.2.3

18. Section 4.2.2.2 of the Development Agreement states, in relevant part, that:

Notwithstanding anything to the contrary in [the Development Agreement] . . . (a) if [MiddleBrook] proposes to revise the Development Plan [which is an exhibit to the Development Agreement] . . . and (b) if after following the procedures in Section 4.2.2.1 the chief executive officers of the Parties fail to agree as to the advisability of such proposed changes to the Development Plan within 30 days after referral of the matter to them, then Par shall have the right for a period of 30 days following the written notice by the chief executive officer of either party to the other Party that the Parties have failed to agree on the proposed changes to the Development Plan (the “**Section 4.2.2.2 Period**”), to terminate [the Development Agreement] upon 30 days’ [sic] prior written notice to [MiddleBrook].”

Development Agreement, § 4.2.2.2.

19. Thus, the Development Agreement unambiguously sets forth that rightful termination of the Development Agreement pursuant to Section 4.2.2.2 requires (i) the Debtor to have proposed revisions to the Development Plan, (ii) the parties to have followed the procedures set forth in Section 4.2.2.1 of the Development Agreement, (iii) written notice to have been provided by the CEO of either Party to the other Party of a failure to agree on proposed changes to the Development Plan (the “**Trigger Notice**”) and (iv) written notice of termination by Par to the Debtor in the 30 day period after provision of the Trigger Notice.

20. Here, none of these steps were followed by Par. The Debtor did not propose revisions to the Development Plan, the parties did not follow the procedures set forth in Section 4.2.2.1 of the Development Agreement, and a Trigger Notice was never sent or effectuated. That is, neither the CEO of Par nor the CEO of the Debtor sent a written notice to the other CEO regarding a failure to agree upon proposed changes to the Development Plan. Instead, Par simply skipped to the last step, and on August 3, 2005, Scott Tarriff, the then-CEO of Par, sent a letter (the “**August 3 Letter**”) to Edward Rudnic, the then-CEO of the Debtor, announcing Par’s unequivocal termination of the Development Agreement. See August 3 Letter (stating purpose of the August 3 Letter is to “formally notify [MiddleBrook] of Par’s termination in accordance with [the Development Agreement]”). The August 3 Letter is attached hereto as Exhibit C.

21. The language of the Development Agreement is clear: termination of the Development Agreement pursuant to Section 4.2.2.2 can only be effectuated after all of the initial steps have been followed and a Trigger Notice has been provided. Because there was no Trigger Notice, or indeed, any discussion regarding proposed changes to the Development Plan as contemplated by Section 4.2.2.2 of the Development Agreement, the August 3 Letter did not constitute termination pursuant to the terms of Section 4.2.2.2 of the Development Agreement.

As a result, Section 4.2.2.3, which only becomes effective if Par “rightfully terminates the Agreement in accordance with the provisions of Section 4.2.2.2,” was never implicated and Par is not entitled to the Section 4.2.2.3 Amount under the Development Agreement. Thus, the Claim must be disallowed and expunged.

22. Indeed, the August 3 Letter, on its face, does not even purport to be a termination of the Development Agreement pursuant to Section 4.2.2.2 thereof, nor does it make any claims under Section 4.2.2.3. It simply states Par’s termination of the Development Agreement and requests confirmation of the Debtor’s “understanding” that Par has terminated the Development Agreement. As such, the August 3 Letter constitutes, at most, simply a mutual agreement to terminate the Development Agreement (or, possibly, an amendment to the Development Agreement terminating same), but the August 3 Letter is most certainly not a termination of the Development Agreement pursuant to Section 4.2.2.2 thereof. Accordingly, the Claim is invalid and the POC should be expunged.

**B. Par Did Not Pay the Debtor At Least \$20,000,000 Prior to Termination of the Development Agreement**

23. Even if the August 3 Letter constituted a “rightful termination” pursuant to the terms of Section 4.2.2.2, Section 4.2.2.3 also provides that the Section 4.2.2.3 Amount becomes due and payable only if “termination [pursuant to Section 4.2.2.2] occurs **after** Par has paid to [MiddleBrook] in cash at least \$20,000,000 in Development Costs.” Development Agreement § 4.2.2.3 (emphasis added). This condition was not met because at the time that Par terminated the Development Agreement pursuant to the August 3 Letter, Par had only made payments to the Debtor totaling \$18,500,000. See Exhibit B to the Development Agreement, § B.10.1; see also August 3 Letter. Exhibit B to the Development Agreement sets forth the agreed upon schedule of payments to be made by Par to the Debtor pursuant to the Development Agreement (the

**“Payment Schedule”**). When Par terminated the Development Agreement, Par had only made the July 1, 2004 – April 1, 2005 payments, which total \$18,500,000. Par cannot dispute this fact as the August 3 Letter itself indicates that the July 1, 2005 payment set forth on the Payment Schedule had not yet been made and that the October 1, 2005 payment was to be canceled. The August 3 Letter further indicates that the July 1, 2005 payment will not be paid until the Debtor acknowledges termination of the Development Agreement by Par.

24. Although Par belatedly made the July 1, 2005 payment, Par’s termination of the Development Agreement occurred before Par had paid in excess of \$20,000,000 in cash to the Debtor. Because the express language of the Development Agreement requires Par to pay the Debtor in excess of \$20,000,000 in cash before termination in order for the Debtor to be obligated with respect to the Section 4.2.2.3 Amount, Par is not entitled to the Section 4.2.2.3 Amount and its Claim must be disallowed and the POC expunged.

**C. Par Has No Claim Because the Debtor Did Not Commercialize the “Products”**

25. Even if Par had “rightfully terminated” the Development Agreement pursuant to Section 4.2.2.2, and even if Par had paid the Debtor \$20,000,000 in cash prior to such termination, and therefore Section 4.2.2.3 potentially applied, the conditions precedent to payment by the Debtor of the Section 4.2.2.3 Amount were never met and will never be met. Section 4.2.2.3 provides that Par is entitled to the Section 4.2.2.3 Amount if “[MiddleBrook] successfully commercializes the Products.” Development Agreement § 4.2.2.3 (emphasis added). The term “Products” is defined under the Development Agreement as “the Adult Product and the Pediatric Product.” Development Agreement § 1.68.



26. To date, the Debtor has only commercialized and sold a single product, MOXATAG, which constitutes the “Adult Product” under the Development Agreement.<sup>2</sup> The Debtor has not developed or commercialized a “Pediatric Product” as that term is defined under the Development Agreement. As such, by the plain terms of the Development Agreement, the Debtor has not “successfully commercialized the Products.” Accordingly, the Debtor has no obligation to pay the Section 4.2.2.3 Amount and the Par Claim is without merit.

**D. Par Has No Claim Because There Are No “Net Profits” On Sales of MOXATAG**

27. Even if (a) Par had “rightfully terminated” the Development Agreement pursuant to Section 4.2.2.2, (b) Par had paid the Debtor at least \$20,000,000 in cash prior to such termination, and (c) the clear and unambiguous language of Section 4.2.2.3 can be read to encompass a right to payment in the event of commercialization of just one product, as opposed to the defined term “Products”, and therefore Section 4.2.2.3 potentially applied, Par’s Claim still fails because the Debtor has never generated “net profits” from the sale of the single product.

28. Par is not entitled to any amounts in accordance with the Development Agreement because the Debtor’s commercialization of the single product, the adult version of MOXATAG, has not generated any “net profits”. Pursuant to Section 4.2.2.3, the Section 4.2.2.3 Amount shall be paid by the Debtor’s making of quarterly payments to Par “equal to 15% of [MiddleBrook’s] *net profits* on sales of the Products in such quarter until [MiddleBrook] has refunded to Par the Section 4.2.2.3 Amount.” Development Agreement § 4.2.2.3 (emphasis added). As discussed above, the Debtor only had sales of a single product pursuant to the Development Agreement, not the Products as set forth in Section 4.2.2.3. Further, even if Par

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<sup>2</sup> As discussed below, the Debtor’s commercialization of MOXATAG was not successful.

were entitled to payment of the Section 4.2.2.3 Amount through quarterly payments of 15% of the Debtor's net profits on the sale of that single product, the Debtor has not generated any net profits on account of MOXATAG to distribute. In fact, to date, the Debtor has suffered a loss of approximately \$151.5 million as shown on the profit and loss statement attached hereto as Exhibit D.<sup>3</sup> Thus, it is clear that, even if Section 4.2.2.3 were operative, Par has no claim against the Debtor pursuant to that section because the Debtor has no net profits on account of the product it sold and, as a result of the Sale, will never have any net profits to distribute to Par.

**E. Par Has No Claim Because The Single Product Has Not Been Successfully Commercialized**

29. Even if one were to disregard the myriad reasons set forth above as to the illegitimacy of the Claim, Par is still not entitled to any amounts in accordance with the Development Agreement because MiddleBrook's commercialization of the single product has not been successful. As discussed in the Declaration of David Becker in Support of Chapter 11 Petition and First Day Motions (the "**Becker Declaration**") [Docket No. 4], despite significant capital investment, the Debtor's commercialization of MOXATAG, which constitutes the "Adult Product" under the Development Agreement, was not successful. The revenues generated from the sale of that product were not in excess of the Debtor's expenses. Had the Debtor continued selling such product, the costs associated with the continued sale would likely have continued to cause significant operating losses. Accordingly, even if Section 4.2.2.3 were operative, Par is not entitled to any amounts because the single product has not been "successfully" commercialized.

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<sup>3</sup> Further, even if Par were to contend that the Debtor's Sale to Victory should be factored into the calculation of net profits, and assuming that 100% of the Sale proceeds could be attributed to the single product that has been commercialized (even though Victory also acquired KEFLEX® and the Debtor's Pulsys® technology in addition to the rights to MOXATAG), and that commercialization of that single product was sufficient, the Debtor's losses would still be approximately \$134.2 million.


## CONCLUSION

30. The terms of the Development Agreement are clear and unambiguous. Par failed to comply with the procedures set forth for termination of the Development Agreement pursuant to Section 4.2.2.2, which renders Section 4.2.2.3 inoperative. Further, even if Section 4.2.2.3 were operative, certain unequivocal conditions precedent to a right of payment in favor of Par with respect to the Section 4.2.2.3 Amount clearly were not been satisfied as: (i) Par did not pay more than \$20,000,000 in cash to the Debtor before termination of the Development Agreement; (ii) the Debtor never successfully commercialized both an “Adult Product” and a “Pediatric Product”; (iii) there have been no net profits on account of the sale of MOXATAG; and (iv) the commercialization of the adult version of MOXATAG – the single product – was not successful.

WHEREFORE, for the above-stated reasons, among others, the Debtor respectfully requests that the Court enter an order substantially in the form attached hereto as Exhibit E, (i) disallowing the Claim and expunging the POC in its entirety, and (ii) granting such other relief as is just and proper.

DATED: August 30, 2010

YOUNG CONAWAY STARGATT &  
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# EXHIBIT A

**DEVELOPMENT AND  
COMMERCIALIZATION AGREEMENT**

This Development and Commercialization Agreement (this "**Agreement**") is made and entered into this 28th day of May, 2004 (the "**Effective Date**"), by and between Advancis Pharmaceutical Corporation, a Delaware corporation ("**Advancis**"), and Par Pharmaceutical, Inc., a Delaware corporation ("**Par**").

WHEREAS, Advancis is the owner of certain patents and know-how relating to formulations for the administration of antibiotics, including its proprietary PULSYS™ technology;

WHEREAS, Advancis has commenced the development of a PULSYS™-based amoxicillin product; and

WHEREAS, Advancis and Par desire to collaborate in the further development and commercialization of a PULSYS™-based amoxicillin product.

NOW, THEREFORE, in consideration of the mutual covenants and promises contained in this Agreement and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Advancis and Par agree as follows:

**ARTICLE I  
DEFINITIONS**

The following terms shall have the following meanings:

- 1.1. "**Adult Product**" means a pharmaceutical presentation of the Compound (a) that utilizes or incorporates PULSYS™, (b) that contains no active pharmaceutical ingredient (including any active pharmaceutical ingredient that acts as an  $\beta$ -lactamase inhibitor) other than the Compound, and (c) that is used or is being developed for the Adult Product Indication, other than formulations of Exhibit A.
- 1.2. "**Adult Product Indication**" means Streptococcal Pharyngitis in adolescents/adults (proposed Phase III Studies protocol 111.301), and any other indication agreed to by the Parties.
- 1.3. "**Advancis Indemnified Parties**" has meaning set forth in Section 13.1.
- 1.4. "**Advancis Know-How**" means Know-How owned by or licensed to Advancis, as of the Effective Date or owned by or licensed to Advancis after the Effective Date, which Know-How relates to, underlies or arises out of Advancis's proprietary technology that is used in the development, manufacture, use or sale of Product.

- 1.5. ***“Advancis Patent Rights”*** means all Patent Rights owned by or licensed to Advancis as of the Effective Date or owned by or licensed to Advancis after the Effective Date, which Patent Rights relate to, underlie or arise out of Advancis’s proprietary technology and that are required or utilized for manufacture, use, or sale of Product.
- 1.6. ***“Advancis Slogan”*** has the meaning set forth in Section 5.4.1.
- 1.7. ***“Affiliate”*** means any Person that directly or indirectly Controls, is Controlled by or is under common Control with either Par or Advancis, as applicable. For purposes of this definition, ***“Control”*** means the power to direct or cause the direction of the management and policies of a Person, whether pursuant to the ownership of voting securities, by contract or otherwise.
- 1.8. ***“Alliance Manager”*** has the meaning set forth in Section 3.1.4.
- 1.9. ***“Baseball Arbitration”*** has the meaning set forth in Section 17.2.2.
- 1.10. ***“Baseball Arbitration Notice”*** has the meaning set forth in Section 17.2.2.
- 1.11. ***“cGMP”*** means the regulatory requirements for current good manufacturing practices promulgated by the FDA under the U.S. Food, Drug and Cosmetic Act and the regulations promulgated thereunder, particularly 21 C.F.R. Section 210 et seq., and 21 C.F.R. Sections 600-610, as the same may be amended from time to time.
- 1.12. ***“Clinical Supplies”*** means supplies of Products, manufactured, packaged and labeled in compliance with cGMP, in such form and dosage as is determined by Advancis pursuant to the Development Plan, and suitable for use in the conduct of pre-clinical and/or human clinical trials of the Products in the United States by the Parties pursuant to the Development Plan.
- 1.13. ***“Collaboration Payments”*** has the meaning set forth in Section 6.2.
- 1.14. ***“Commercialization”*** means the marketing, promotion, advertising, selling and/or distribution of Products in the United States after Regulatory Approval has been obtained. The term ***“Commercialize”*** has a corresponding meaning.
- 1.15. ***“Commercialization Plan”*** has the meaning set forth in Section 5.2.1.
- 1.16. ***“Commercialization Program”*** means the Commercialization program conceived, planned, organized, and performed by the Parties for the purpose of bringing the Products to market for sale in the United States, in accordance with the Commercialization Plan.
- 1.17. ***“Commercially Reasonable Efforts”*** means the efforts and resources that would reasonably be used (including the promptness with which such efforts and resources would be applied) in the pharmaceutical industry for the diligent

development, manufacture and commercialization of a pharmaceutical product of similar market and profit potential and at a similar stage in development or product life as compared to the Product. The term "*Commercially Reasonable*" has a corresponding meaning.

- 1.18. "*Commercial Supplies*" means supplies of Product, manufactured, packaged and labeled in compliance with cGMP, in such form and dosage as is determined by Advancis pursuant to the Development Plan, and suitable for Commercialization in the United States by the Parties pursuant to the terms of this Agreement and the annual Commercialization Plans. As used herein, "Commercial Supplies" includes Samples.
- 1.19. "*Commercialization Parameters and Detailing Schedule*" means the schedule, attached to this Agreement as Exhibit C, that addresses the Detailing and Promotional activities for each Party during the Term. The objectives of Exhibit C automatically shall be incorporated in and be part of the initial Commercialization Plan upon approval of the initial Commercialization Plan, and may be amended solely in conjunction with the amendment of the initial Commercialization Plan.
- 1.20. "*Compound*" means the compound amoxicillin, including all racemates, chelates, complexes, enantiomers, diastereoisomers, salts, bases, esters, hydrates, solvates, polymorphs, crystal forms, crystal habits, prodrugs, isotopic or radiolabeled equivalents, metabolites, or the like, thereof and all mixtures of any of the foregoing.
- 1.21. "*Confidential Information*" means information of a Party that is disclosed to or obtained by the other Party (including information obtained by a Party as a result of access to the facilities of the other Party) either prior to or during the term of this Agreement which information (a) is non-public, confidential or proprietary in nature, including trade secrets, financial data, product information, manufacturing methods, market research data, marketing plans, identity of customers, nature and source of raw materials, product formulation and methods of producing, testing and packaging, and (b) relates to the disclosing Party's past, present or future research, development or Commercialization activities; provided, however, that Confidential Information shall not include information that a Party can demonstrate by written evidence: (i) is in the public domain other than as a result of a breach by such Party (or any of its Affiliates) of its obligations of confidentiality contained herein; (ii) was known by the receiving Party prior to receipt from the disclosing Party; (iii) has been developed by the receiving Party independent of any Confidential Information of the other Party; or (iv) was subsequently, lawfully and in good faith obtained by the receiving Party on a non-confidential basis from a third party that was not under an obligation to treat such information in a confidential manner and had a lawful right to make such disclosure. Without limiting the foregoing, the terms of this Agreement, including the Development Plan and each Commercialization Plan, shall constitute "Confidential Information" hereunder.



- 1.22. "**Damages**" has the meaning set forth in Section 11.2.3.
- 1.23. "**Defaulting Party**" has the meaning set forth in Section 12.2.1.
- 1.24. "**Detail**" has the meaning set forth in Exhibit C.
- 1.25. "**Detailing Priorities**" has the meaning set forth in Exhibit C.
- 1.26. "**Detailing Requirements**" has the meaning set forth in Exhibit C.
- 1.27. "**Development and Manufacturing Subcommittee**" has the meaning set forth in Section 3.3.
- 1.28. "**Development Costs**" has the meaning set forth Exhibit B.
- 1.29. "**Development Funding Gap**" means the excess of (a) the aggregate amount of Development Costs incurred by Advancis from the Effective Date over (b) the aggregate amount of the installment payments made by Par after the Effective Date pursuant to Section B.10 of Exhibit B.
- 1.30. "**Development Plan**" means the plan for the implementation and funding of the Development Program mutually agreed to by the Parties, which plan is designed to generate the development, clinical and regulatory information required for filing NDAs and to further support the development of Products for the purpose of obtaining Regulatory Approvals, and any revisions thereto that are made in accordance with this Agreement.
- 1.31. "**Development Program**" means the research and development program conceived, planned, organized, controlled and performed by Advancis to develop the Products for Commercialization, in accordance with the Development Plan. The Development Program includes all activities related to Product Studies, toxicology, formulation, process development, quality assurance/quality control, and regulatory affairs for a Product in connection with obtaining Regulatory Approvals of such Product.
- 1.32. "**Draft Plan**" has the meaning set forth in Section 5.2.1.
- 1.33. "**Effective Date**" has the meaning set forth in the preamble.
- 1.34. "**FDA**" means The Food and Drug Administration of the United States Department of Health and Human Services, or any successor agency(ies) thereof performing similar functions.
- 1.35. "**Financial Planning Schedule**" means the financial planning, accounting and reporting schedule of the Parties relating to the costs, budgeting, funding, and related financial and accounting matters relevant to this Agreement, a copy of which is attached to this Agreement as Exhibit B.

- 1.36. “**FTE**” has the meaning set forth in Exhibit B.
- 1.37. “**FTE Rate**” has the meaning set forth in Exhibit B.
- 1.38. “**Indemnitor**” has the meaning set forth in Section 13.3.
- 1.39. “**Indemnitee**” has the meaning set forth in Section 13.3.
- 1.40. “**Indications**” means the Adult Product Indication and the Pediatric Product Indications.
- 1.41. “**Invention**” means any invention or discovery, whether patentable or unpatentable, made or discovered while performing under this Agreement.
- 1.42. “**Invoice**” has the meaning set forth in Exhibit B.
- 1.43. “**Finance Subcommittee**” has the meaning set forth in Section 3.5.
- 1.44. “**Know-How**” means all data, experience, inventions, discussions, trade secrets, compositions of matter and methods, procedures, processes, materials, know-how or other scientific or technical information of any kind of a Party, whether existing prior to or during the term of this Agreement, and whether or not patentable or confidential, including biological, chemical, biochemical, toxicological, pharmacological, metabolic, formulation, clinical, analytical, and stability information and data.
- 1.45. “**Losses**” has the meaning set forth in Section 13.1.
- 1.46. “**Manufacturing Costs**” has the meaning set forth in Exhibit B.
- 1.47. “**Marketing Distributors**” means a Third Party to whom Par or its Affiliate has granted a right to distribute Products.
- 1.48. “**NDA**” means a New Drug Application as defined in the United States Federal Food, Drug and Cosmetic Act and applicable regulations promulgated thereunder as amended from time to time.
- 1.49. “**Net Sales of Products**” has the meaning set forth in Exhibit B.
- 1.50. “**Non-Defaulting Party**” has the meaning set forth in Section 12.2.1.
- 1.51. “**Office of New Drugs**” means the Office of New Drugs within the Office of the Center Director of the FDA’s Center for Drug Evaluation and Research.
- 1.52. “**Operating Profits**” has the meaning set forth in Exhibit B.
- 1.53. “**Option**” has the meaning set forth in Section 2.2.
- 1.54. “**Option Candidate**” has the meaning set forth in Section 2.2.

- 1.55. ***“Par Indemnified Parties”*** has meaning set forth in Section 13.2.
- 1.56. ***“Party”*** or ***“Parties”*** means Advancis and/or Par, as applicable.
- 1.57. ***“Patent Rights”*** means any of the following: (a) United States patents; (b) United States patent applications (both provisional and non-provisional), PCT patent applications, and divisionals, continuations and claims of continuation-in-part applications which shall be directed to subject matter specifically described in such United States and/or PCT patent applications, and the resulting patents (whether such divisionals, continuations or continuation-in-part applications are based upon a United States patent, United States patent application or PCT application); (c) any patents resulting from reissues or reexaminations of the United States patents described in (a) and (b) above; (d) foreign patents; (e) foreign patent applications and, to the extent applicable, divisionals, continuations and claims of continuation-in-part applications which shall be directed to subject matter specifically described in such foreign patent applications, and the resulting patents (whether such divisionals, continuations or continuation-in-part applications are based upon a foreign patent application or a foreign patent); and (f) any foreign patents, resulting from foreign procedures similar to United States reissues and reexaminations, of the foreign patents and applications described in (d) and (e) above.
- 1.58. ***“PDMA”*** means the Prescription Drug Marketing Act of 1987.
- 1.59. ***“Pediatric Product”*** means the pharmaceutical presentation of the Compound (a) that utilizes or incorporates PULSYS™, (b) that contains no active pharmaceutical ingredient (including any active pharmaceutical ingredient that acts as a  $\beta$ -lactamase inhibitor) other than the Compound, and (c) that is used or is being developed for the Pediatric Product Indications, other than formulations of Exhibit A.
- 1.60. ***“Pediatric Product Indications”*** means (i) Streptococcal Pharyngitis (proposed Phase III Studies protocol 231.301); (ii) acute otitis media (proposed Phase III Studies protocol 231.302); and (c) any other indications agreed to by the Parties.
- 1.61. ***“Person”*** means an individual, partnership, joint venture, association, corporation, limited liability company and any other form of business organization, government, regulatory or governmental agency, commission, department or instrumentality.
- 1.62. ***“Phase III Study(ies)”*** means that portion of the Development Program that provides for large scale, pivotal, clinical studies that (a) are conducted in a number of patients that is intended to be sufficient to obtain a definitive evaluation of the therapeutic efficacy and safety of a Product in patients for a given Indication and (b) that are needed to evaluate the overall risk-benefit relationship of the Products and to provide adequate basis for obtaining requisite Regulatory Approvals.

- 1.63. ***“Preliminary Commercialization Plan”*** means the Commercialization Plan presented to Par by Advancis on April 14, 2004.
- 1.64. ***“Premarketing Costs”*** has the meaning set forth in Exhibit B.
- 1.65. ***“Premarketing Program”*** means the program to be conceived, planned, organized and performed by the Parties from and after the Effective Date for the purpose of bringing the Products to market for sale in the United States after Regulatory Approval for such sale has been obtained, as set forth in the Commercialization Plan.
- 1.66. ***“Principal Trademark”*** has the meaning set forth in Section 5.4.1.
- 1.67. ***“Product Infringement”*** has the meaning set forth in Section 11.2.3.
- 1.68. ***“Products”*** means the Adult Product and the Pediatric Product.
- 1.69. ***“Product Sales Force”*** has the meaning set forth in Exhibit C.
- 1.70. ***“Product Sales Force Costs”*** has the meaning set forth in Exhibit B.
- 1.71. ***“Product Studies”*** means clinical studies, pre-clinical studies, safety studies, epidemiological studies, modeling and pharmacoeconomic studies, in each case including any ancillary or incidental development, investigation or research schemes pertaining thereto, that are designed (a) to support Regulatory Approval for the Products or (b) to support publications, Promotional and educational activities, future labeling changes or new Indications for the Products.
- 1.72. ***“Product Trademarks”*** has the meaning set forth in Section 5.4.1.
- 1.73. ***“Program Developments”*** means all Inventions, discoveries, Patent Rights, Know-How, copyrights and works of authorship that are made, developed, created, conceived or reduced to practice in connection with or relating to the Development Program or Commercialization Program during the term of this Agreement, regardless of whether the Invention, discovery, Know-How, or work is patentable and regardless of whether it was made solely by an employee or agent of Par, solely by an employee or agent of Advancis, or jointly by Par and Advancis.
- 1.74. ***“Promote”*** has the meaning set forth Exhibit C. The term ***“Promotional”*** has a corresponding meaning.
- 1.75. ***“Promotion Costs”*** has the meaning set forth in Exhibit B.
- 1.76. ***“Promotional Materials”*** has the meaning set forth in Section 5.2.4.1.
- 1.77. ***“Proposal”*** has the meaning set forth in Section 17.2.2.

- 1.78. ***“Proposed Phase III Protocols”*** means, collectively, Advancis’s current proposals for Phase III Studies protocols for the Products with respect to the Indications.
- 1.79. ***“PULSYS™”*** means drug delivery technology involving front-loaded, sequential bursts, or pulses, of a pharmaceutical product.
- 1.80. ***“Recall”*** has the meaning set forth in Section 16.1.
- 1.81. ***“Regulatory Approval”*** means approval by the FDA to market the Products in the United States, including the issuance by the FDA of an action letter indicating that an NDA is approved, final FDA approval of Promotional materials for Products sufficient for launch, and final FDA approval of manufacturing processes and facilities for Products sufficient that Commercial Supplies of Products can be manufactured prior to launch.
- 1.82. ***“Representatives”*** has the meaning set forth in Section 10.1 below.
- 1.83. ***“Sales and Marketing Subcommittee”*** has the meaning set forth in Section 3.4.
- 1.84. ***“Sales Representatives”*** has the meaning set forth in Exhibit C.
- 1.85. ***“Sample”*** means a Product packaged and distributed to a Target Prescriber as a complementary trial for use with patients in the United States and in accordance with the PDMA.
- 1.86. ***“Section 4.2.2.2 Period”*** has the meaning set forth in Section 4.2.2.2.
- 1.87. ***“Section 4.2.2.3 Amount”*** has the meaning set forth in Section 4.2.2.3.
- 1.88. ***“Subcommittee”*** has the meaning set forth in Section 3.1.5.
- 1.89. ***“Supply Agreement”*** has the meaning set forth in Section 8.3.
- 1.90. ***“Targeted Prescribers”*** has the meaning set forth in Exhibit C.
- 1.91. ***“Term”*** has the meaning set forth in Section 12.1 below.
- 1.92. ***“Third Party”*** means any party other than Par, Advancis and their respective Affiliates.
- 1.93. ***“Territory”*** means North America and Europe, subject to the provisions of Exhibit D.
- 1.94. ***“Total Details”*** means the aggregate number of Details and the Detail Priorities therefor for the applicable calendar year as set forth in the Commercialization Plan for the applicable calendar year.

- 1.95. "**Valid Claim**" means either (a) a claim contained in an issued and unexpired patent which constitutes Advancis Patent Rights which claim (i) has not been held unenforceable, unpatentable or invalid by a governmental agency or a court of competent jurisdiction in a decision which is unappealable or which was not appealed within the time allowed for appeal, and (ii) has not been admitted to be unenforceable, unpatentable or invalid through abandonment, reissue, disclaimer or otherwise, or (b) a claim contained in a pending patent application which constitutes Advancis Patent Rights which claim (i) has not been abandoned or finally rejected by Advancis without the possibility of appeal or re-filing and (ii) has been under examination for less than four (4) years.

## **ARTICLE II**

### **SCOPE OF THE COLLABORATION**

**2.1 Products.** The Parties agree, pursuant and subject to the terms of this Agreement, that the goals of their collaboration under this Agreement are to develop the Products to obtain Regulatory Approval for such Products in the Territory in commercially-significant indications and to Commercialize such Products in the Territory as soon as reasonably practicable. Except as otherwise expressly provided herein, each Party shall use Commercially Reasonable Efforts to perform its tasks and obligations under this Agreement, including under the Development Plan and each Commercialization Plan, and each Party shall cooperate with the other Party in the performance of such other Party's tasks and obligations hereunder.

**2.2 Option.** (a) During the Term, Advancis agrees to select one pharmaceutical product that uses PULSYS™ and as to which proof of principle has been established ("Option Candidate"); and Advancis agrees to use Commercially Reasonable Efforts to complete a proof of principle for such a product. Advancis shall provide Par with written notice of the Option Candidate and provide Par information reasonably available to Advancis, including an estimate of the cost for developing and obtaining regulatory approval therefor that is reasonably required by Par to make a determination as to whether or not to enter into an agreement with Advancis with respect to such Option Candidate. The delivery of such notice shall automatically grant to Par an exclusive Option to enter into an agreement with Advancis with respect to such Option Candidate (the "Option"). Within 60 days after Par's receipt of notification of the Option Candidate from Advancis, Par shall have the right to (a) exercise the Option by delivering to Advancis a written notice of exercise; or (b) reject the Option. If Par fails to exercise the Option within 60 days after Par's receipt of notification of the Option Candidate from Advancis, the Option shall be deemed rejected and shall expire. If Par exercises the Option, Advancis shall negotiate exclusively and in good faith with Par the terms of a development and commercialization agreement for the Option Candidate for a period of sixty (60) days following exercise of the Option (the "Candidate Agreement"). The Candidate Agreement shall be on terms substantially similar to those of this Agreement and shall include the following terms: (i) Advancis is the Selling Party and Par shall co-promote, with each Party having the right to perform one-half of the details and neither Party shall be required to perform more than sixty-percent of the details and neither party shall perform less than forty percent of the details, (ii) the Parties shall equally share profits, (iii) the Parties shall equally share premarketing and promotion expenses, (iv) each Party shall bear the cost and expense of its sales force, (v) Par

shall fund on an on-going basis one-hundred percent of the development costs, and (vi) Par shall pay to Advancis an upfront fee of five million dollars (\$5,000,000.00.)

If at the end of the sixty (60) day period, the Parties have not reached agreement as to all of the terms and conditions of the Candidate Agreement, then at any time thereafter either Party shall have the right to submit to Baseball Arbitration the terms and conditions as to which agreement has not been reached. It is expressly understood and agreed that the terms that have been set forth in Section 2.2(i)-(vi) shall be included in the Candidate Agreement and such terms may not be varied or changed by the Baseball Arbitration.

(b) If an Option is rejected by Par pursuant to Section 2.2(a) with respect to an Option Candidate, then Advancis agrees to offer Par one other Option Candidate pursuant to Section 2.2(a). It is expressly understood that this Section 2.2(b) applies only once.

**2.3 Non-Competition.** During the Term, and except as through the Collaboration pursuant to this Agreement neither party for the Territory shall develop, market, sell or distribute any pharmaceutical product that requires approval from the Office of New Drugs, wherein the sole active pharmaceutical ingredient in such product is the compound amoxicillin, including chelates, complexes, hydrates, solvates, polymorphs or other crystal forms or habits, or radiolabeled equivalents or any mixture of the foregoing. Notwithstanding the foregoing, it is expressly agreed that this Section 2.3 does not apply to any formulations of Exhibit A.

### **ARTICLE III MANAGEMENT OF THE COLLABORATION**

#### **3.1 Executive Committee.**

**3.1.1. Establishment.** The Parties hereby establish an Executive Committee consisting of six (6) members, three (3) of whom shall be Par designees and three (3) of whom shall be Advancis designees. Each of the Executive Committee members shall have appropriate expertise to oversee the Parties' performance of this Agreement and at least two (2) designees of each Party must have the rank of Vice President or higher within such Party; provided, that neither Party shall designate its chief executive officer to serve on the Executive Committee. The initial Executive Committee members shall be designated by each Party within one week of the Effective Date. Each Party shall have the right at any time and from time to time to designate a replacement, on a permanent or temporary basis, for any or all of its previously-designated members of the Executive Committee. At the beginning of each calendar year during the Term, each Party shall appoint one of its designees to serve as a Co-Chair of the Executive Committee. The initial Co-Chairs shall be designated by each Party within one week of the Effective Date.

#### **3.1.2. Meetings and Procedures.**

**3.1.2.1** The Executive Committee shall meet at least once per calendar quarter, and more frequently at the request of either Party or as required to resolve disputes, disagreements or deadlocks, on such dates, and at such places and times, as the Parties shall agree; provided that the Parties shall use their Commercially Reasonable Efforts to cause the first meeting of the Executive Committee to occur within thirty (30) days after the Effective Date.

The two Co-Chairs shall cooperate to send a notice and agenda for each meeting of the Executive Committee to all members of the Executive Committee reasonably in advance of the meeting. The location of regularly-scheduled Executive Committee meetings shall alternate between the offices of the Parties, unless otherwise agreed. The members of the Executive Committee also may convene or be polled or consulted from time to time by means of telephone conference, video conference, electronic mail or correspondence and the like, as deemed necessary or appropriate by the Co-Chairs. The Party hosting any Executive Committee meeting shall appoint one person (who need not be a member of the Executive Committee) to attend the meeting and record the minutes of the meeting in writing. Such minutes shall be circulated to the members of the Executive Committee promptly following the meeting for review and comment.

**3.1.2.2** All decisions of the Executive Committee shall be made by unanimous vote or unanimous written consent of both Parties, with each Party having, collectively, among its respective designees, one vote in all decisions. The members of the Executive Committee shall use Commercially Reasonable Efforts to decide all matters assigned to the Executive Committee under this Agreement or otherwise referred to it by mutual agreement of the Parties. Any matter that is not decided shall be subject to resolution by the chief executive officers of the Parties pursuant to Section 17.1 and, thereafter, by arbitration in accordance with Section 17.2.2.

**3.1.3. Purposes and Powers.** The principal purpose of the Executive Committee shall be to approve the overall strategy for the Parties' collaboration hereunder and provide guidance and direction as provided herein. Subject to the express rights of the Parties as set forth herein, the functions of the Executive Committee shall include:

**3.1.3.1** Acting as liaison between the Parties to ensure that they are informed of the ongoing progress of the Development Program and the Premarketing Program;

**3.1.3.2** Reviewing and approving the division of responsibilities between the Parties as set forth herein and as expanded from time to time in furtherance of the goals of the Parties' collaboration;

**3.1.3.3** Reviewing and approving any proposed amendments to the Commercialization Plans and, reviewing proposed amendments to the Development Plan;

**3.1.3.4** Establishing and empowering Subcommittees and overseeing their work on an ongoing basis;

**3.1.3.5** Reviewing and approving the work of the Finance Subcommittee on all financial aspects of the Commercialization Plans and with respect to the Development Plan review only on an ongoing basis, including funding requirements, budget comparisons, expense levels and financial results;

**3.1.3.6** Reviewing and approving activities related to manufacturing of the Products and the selection of manufacturer(s) for the Products;



**3.1.3.7** Reviewing and approving annual marketing and sales budgets for the Products based on the then-current Commercialization Plan, and determining any Phase IV clinical support to be provided by the Parties (including scope and strategic direction);

**3.1.3.8** In accordance with the procedures established below, resolving disputes, disagreements and deadlocks between the Parties;

**3.1.3.9** Performing such other responsibilities as may be assigned to the Executive Committee pursuant to this Agreement or as may be mutually agreed upon by the Parties from time to time.

**3.1.3.10** Reviewing and final approval of each Draft Plan and/or revisions and/or amendments thereto and any amendments to any Commercialization Plan.

**3.1.4. Alliance Managers.** The Co-Chair appointed by each Party will designate another person representing the same Party who has a general understanding of clinical, regulatory, commercial and manufacturing issues to act as the Alliance Manager for such Party (each, an "*Alliance Manager*"). The role of the Alliance Managers shall be to serve as a single point of contact within each Party to facilitate communication, collaboration and dispute resolution between the Parties. The Alliance Managers shall have access to the decision-makers within their respective Parties and shall have the right to attend (but not to vote at) all meetings of the Subcommittees. The Co-Chairs shall inform the Alliance Managers of potential or pending disagreements and key decisions. The Alliance Managers shall work together to resolve issues and potential disputes with a view to enabling the Executive Committee and the Subcommittees to reach unanimous decisions and to avoiding escalation of such matters.

**3.1.5. Subcommittees.** In addition to the Development and Manufacturing Subcommittee, the Sales and Marketing Subcommittee and the Finance Subcommittee (as defined below), the Executive Committee may from time to time, in its sole discretion, create one or more joint subcommittees (each, a "*Subcommittee*"), each to consist of an equal number of designees of each Party, for the purpose of implementing directives of the Executive Committee and strategies and programs that support and implement the Development Program, the Commercialization Program and the Premarketing Program. Such Subcommittees shall meet at such times and locations and shall otherwise be governed by and subject to such rules, processes and procedures as shall be approved by the Executive Committee. Except as expressly provided herein or in a written delegation of authority by the Executive Committee, no Subcommittee shall have the right to exercise any decision-making authority of the Executive Committee.

**3.1.6. Expenses.** Each Party shall bear the cost of travel and other expenses relating to the attendance of its designees at all meetings of the Executive Committee and all Subcommittee(s).

**3.1.7. Nondisclosure Agreement.** All designees of each Party serving on the Executive Committee and any Subcommittee(s) shall as a condition to such service execute a nondisclosure and assignment of inventions agreement in form and substance reasonably satisfactory to the Parties.

**3.2 Development and Manufacturing Subcommittee.** Within thirty (30) days after the Effective Date, the Parties shall establish a Subcommittee (the “*Development and Manufacturing Subcommittee*”) with responsibility for (a) overseeing the manufacture of all Products and all Compound used therein, (b) reviewing proposed additions to the Development Plan for presentation to the Executive Committee (other than budgetary, expense, and other financial matters, which shall be presented by the Finance Subcommittee); (c) reviewing proposed changes to the Development Plan and receiving updates regarding Advancis’s execution of the Development Program; (d) recommending the priority and design of clinical trials for new Indications and formulations; (e) recommending the priority of actions to be taken with respect to seeking Regulatory Approval for the Products; (f) reviewing third party manufacturing and supply agreements with respect to the Products; (g) assisting to identify responses to potential interruptions in the supply of Compound or Products; (h) supervising audits of any third party suppliers of Compound or Products; (i) supervising implementation of improvements in quality control and assurance, cost reduction initiatives, logistics initiatives, environmental, health and safety initiatives and similar programs; and (j) performing such other duties as may be assigned under this Agreement or as may be delegated to the Development and Manufacturing Subcommittee by the Executive Committee; provided, that nothing in this Section 3.3 shall limit the rights or obligations of the Parties under Articles IV and VIII or under the Supply Agreement. Each Party shall appoint two designees to the Development and Manufacturing Subcommittee each of whom shall have expertise and experience in the areas of pharmaceutical development and manufacturing. Either Party may replace any or all of its designees on the Development and Manufacturing Subcommittee at any time upon written notice to the other Party, and any member of the Development and Manufacturing Subcommittee may designate a suitable proxy to perform the functions of that member at any time. In addition, the Development and Manufacturing Subcommittee shall seek to act with the unanimous consent of all members of the Development and Manufacturing Subcommittee. In the event that the Development and Manufacturing Subcommittee members do not reach consensus with respect to a matter that is within the purview of the Development and Manufacturing Subcommittee, the Development and Manufacturing Subcommittee designees of each Party shall collectively have one vote for purposes of decision-making hereunder with respect to such matters, with decisions made by unanimous vote of both Parties. If the votes of the Development and Manufacturing Subcommittee are split on any matter, such matter shall be referred to the Executive Committee for decision.

**3.3 Sales and Marketing Subcommittee.** Within thirty (30) days after the Effective Date, the Parties shall establish a Subcommittee (the “*Sales and Marketing Subcommittee*”) with responsibility for (a) preparing Draft Plans for each calendar year and, in conjunction with the Finance Subcommittee, annual budgets; (b) monitoring compliance with and implementation of the then-current Commercialization Plan; (c) formulating proposed additions or revisions to the then-current Commercialization Plan for presentation to the Executive Committee (other than budgetary, expense, and other financial matters, which shall be presented by the Finance Subcommittee); (d) developing a life cycle management plan in conjunction with the Development and Manufacturing Subcommittee, (e) developing and discussing strategies for the promotion and marketing of Products in the United States, including allocation of responsibility for marketing and commercialization activities; (f) identifying publication strategies and scheduling participation in key scientific and clinical meetings and similar events for the Products (g) determining the launch dates for the Products, (h) determining the prices for the

Products and any of discounts that may be offered by the Parties, (i) preparing short- and long-term sales forecasts, (j) presenting forecasts and results of all Commercialization efforts in the Territory to the Executive Committee as needed but not less than once per quarter, (k) overseeing all Recalls, market withdrawals and other corrective actions related to the Products in the Territory, (l) developing positioning and marketing strategies consistent with the then-current Commercialization Plan, including any decision to seek or include any new Indications for the Products, (m) developing advertising and promotional materials for use by the Product Sales Force, (n) planning and overseeing medical education programs, (o) developing and implementing a publication or data dissemination strategy, (p) creating product presentations and exhibits for major medical meetings, (q) scheduling joint meetings of the Product Sales Force, (r) overseeing and implementing Phase IV programs, (s) reviewing and adjusting Targeted Prescriber lists, (t) delegating responsibility for interacting with advertising agencies and medical education agencies and (u) performing such other duties as may be assigned under this Agreement or as may be delegated to the Sales and Marketing Subcommittee by the Executive Committee; provided, that nothing in this Section 3.3 shall limit the rights or obligations of the Parties in this Agreement. Each Party shall appoint three designees to the Sales and Marketing Subcommittee, each of whom shall have expertise and experience in the areas of marketing, promotion, advertising and sales. Either Party may replace any or all of its designees on the Sales and Marketing Subcommittee at any time upon written notice to the other Party, and any member of the Sales and Marketing Subcommittee may designate a suitable proxy to perform the functions of that member at any time. In addition, the Sales and Marketing Subcommittee shall seek to act with the unanimous consent of the members of the Sales and Marketing Subcommittee. In the event that all of the Sales and Marketing Subcommittee members do not reach consensus with respect to a matter that is within the purview of the Sales and Marketing Subcommittee, the Sales and Marketing Subcommittee designees of each Party shall collectively have one vote for purposes of decision-making hereunder with respect to such matters, with decisions made by unanimous vote of both Parties. If the votes of the Sales and Marketing Subcommittee are split on any matter, such matter shall be referred (by way of the Alliance Managers) to the Executive Committee for decision.

**3.4 Finance Subcommittee.** Within thirty (30) days after the Effective Date, the Parties shall establish a Subcommittee (the "*Finance Subcommittee*") with responsibility for administering all financial, budgetary and accounting matters that arise in connection with Development Program, the Commercialization Program and the Premarketing Program and performing such other duties as may be assigned under this Agreement or as may be delegated to the Finance Subcommittee by the Executive Committee; provided, that nothing in this Section 3.4 shall limit the rights or obligations of the Parties in this Agreement. Each Party shall appoint a senior financial manager and one other designee to the Finance Subcommittee, each of whom shall have expertise in the areas of accounting, cost allocation, budgeting and financial reporting. Either Party may replace any or all of its designees on the Finance Subcommittee at any time upon written notice to the other Party, and any member of the Finance Subcommittee may designate a suitable proxy to perform the functions of that member at any time. In addition, the Finance Subcommittee shall seek to act with the unanimous consent of all members of the Finance Subcommittee. In the event that the Finance Subcommittee members do not reach consensus with respect to a matter that is within the purview of the Finance Subcommittee, the Finance Subcommittee designees of each Party shall collectively have one vote for purposes of decision-making hereunder with respect to such matters, with decisions made by unanimous vote

of both Parties. If the votes of the Finance Subcommittee are split on any matter, such matter shall be referred (by way of the Alliance Managers) to the Executive Committee for decision.

**3.5 Specific Provisions Control.** Nothing in this Article III shall apply to or limit in any way the decisions made by a Party with respect to matters for which any other provision of this Agreement expressly grants such Party sole decision-making authority.

**3.6** The committees and subcommittees cannot make any decision that amends the terms and conditions of this Agreement or that changes the rights and obligations of the Parties under this Agreement.

#### **ARTICLE IV DEVELOPMENT PROGRAM**

**4.1 Advancis Responsibility and Control.** Within one week of the Effective Date the Parties shall mutually agree in writing upon a Development Plan. Subject to the Development Plan and the other terms and conditions contained in this Agreement, Advancis shall have the sole control and responsibility for executing the Development Program, including planning, strategy, administrative management, overall fiscal control and execution of the Development Program. The Development Program shall be conducted at and coordinated from the facilities of Advancis. Advancis shall keep Par apprised of the status of the Development Program through the Development and Manufacturing Subcommittee and, as appropriate, the Executive Committee. Advancis shall comply, and shall require all of its third party agents and contractors, if any, to comply, with all applicable laws in the conduct of the Development Program.

#### **4.2 Development Plan.**

**4.2.1 Conduct by Advancis.** Advancis shall use Commercially Reasonable Efforts to conduct the Development Program in accordance with the Development Plan. Notwithstanding the foregoing or any other provision of this Agreement, Par acknowledges and agrees that (a) the Development Program is experimental in nature; (b) Advancis does not guaranty that the Development Program will be successful or that Regulatory Approval will be obtained for any Product and (c) except for a failure of Advancis to use Commercially Reasonable Efforts, Advancis will have no liability to Par as a result of any failure to achieve or delay in achieving the Development Plan, or any milestones therein, nor shall Advancis have any liability to Par as a result of any failure to obtain or delay in obtaining Regulatory Approval.

#### **4.2.2 Revisions to Development Plan.**

**4.2.2.1** During the Term, Advancis may revise the Development Plan at any time and from time to time in its discretion upon notice to Par in response to developments during the Term, including with respect to the status of clinical trials, Regulatory Approval efforts, financial matters, and the like; provided that Par shall have 30 days after receiving any proposed material revisions (including any revisions reasonably likely to adversely affect the budgets, timeline, Product profile or development strategy of the Products) from Advancis in which to request in writing that the revised Development Plan be submitted for the review of the

Development and Manufacturing Subcommittee. If Par does not provide a written request for review by the Development and Manufacturing Subcommittee to Advancis within such 30 day period, then the proposed Development Plan shall be deemed accepted by Par. If Par does request in writing that the Development and Manufacturing Subcommittee review the proposed Development Plan within such 30 day period, then Par and Advancis shall promptly convene a meeting of the Development and Manufacturing Subcommittee to review and approve such proposed Development Plan in accordance with Section 3.2, subject to (a) referral of such matter to the Executive Committee, if the Development and Manufacturing Subcommittee fails to reach a decision and (b) submission of such matter to the chief executives of the parties in accordance with Section 17.1 if the Executive Committee fails to reach a decision, if the chief executives fail to reach a decision in thirty (30) days, the then proposed Development Plan shall become the Development Plan.

**4.2.2.2** Notwithstanding anything to the contrary in this Agreement (including the provisions of Section 3.1 and Section 4.2.2.1 requiring submission of disputes to arbitration), (a) if Advancis proposes to revise the Development Plan in a manner that would (i) cause any Development Cost to increase by 25% or more over the corresponding Development Cost as then budgeted or (ii) cause the anticipated marketing of all indications of all Products to be delayed by more than two (2) years from the estimated Product Regulatory Approval Date set forth in the Development Plan as first agreed to by the Parties and (b) if after following the procedures in Section 4.2.2.1 the chief executive officers of the Parties fail to agree as to the advisability of such proposed changes to the Development Plan within 30 days after referral of the matter to them, then Par shall have the right for a period of 30 days following the written notice by the chief executive officer of either party to the other Party that the Parties have failed to agree on the proposed changes to the Development Plan (the "**Section 4.2.2.2 Period**"), to terminate this Agreement upon 30 days' prior written notice to Advancis. If the Section 4.2.2.2 Period expires without Par delivering a written notice of termination to Advancis, then this Agreement shall remain in force.

**4.2.2.3** In the event that Par rightfully terminates this Agreement in accordance with the provisions of Section 4.2.2.2, then (i) no Development Funding Gap amounts shall be due or payable; and (ii) if such termination occurs after Par has paid to Advancis in cash at least \$20,000,000 in Development Costs and Advancis successfully commercializes the Products then Advancis shall reimburse Par for one-half of such amount (the "**Section 4.2.2.3 Amount**") following the successful commercialization of the Products by making quarterly payments to Par equal to 15% of Advancis' net profits on sales of the Products in such quarter until Advancis has refunded to Par the Section 4.2.2.3 Amount.

**4.2.3** Any and all additional development costs explicitly included in the Development Plan revised in accordance with Section 4.2.2 of this agreement shall constitute Development Costs, subject only to the rights of the Parties under Section 4.2.2.3 and Section 12.3 if this Agreement is terminated pursuant to Section 4.2.2.

### **4.3 Clinical and Regulatory Approval.**

**4.3.1 Conduct by Advancis.** Under Advancis's direction and control, Advancis agrees to use Commercially Reasonable Efforts (a) to conduct required clinical trials of

the Products and obtain Regulatory Approval in accordance with the Development Plan and (b) to include Par in such efforts in a consultative capacity; provided, however, for purposes of clarity, Par shall not have the right to direct or control Advancis' conduct of such clinical trials.

**4.3.2 Regulatory Submissions.** The Parties acknowledge that the Products have not been reviewed or approved for sale or use for any purpose by any governmental or regulatory body. Advancis shall prepare any required application(s) for Regulatory Approval. Advancis shall own in their entirety (a) all clinical data and reports related to Product Studies including clinical trials for the Products and (b) all NDAs and other Regulatory Approvals for Products. Advancis shall use its Commercially Reasonable Efforts to inform Par of all communications with the FDA and to provide copies of FDA submissions to the Development and Manufacturing Subcommittee prior to their submission to FDA. The Parties shall cooperate in good faith with respect to, and Advancis shall use its Commercially Reasonable Efforts to enable representatives of Par to attend all formal meetings with the FDA relating to regulatory approval of the Products. The Parties shall cooperate in good faith with respect to the conduct of any inspections by any regulatory authority of a Party's site and facilities related to the Products. To the extent either Party receives written or material oral communication from the FDA or any other regulatory authority relating to any Regulatory Approval process with respect to the Products, the Party receiving such communication shall notify the other Party and provide a copy of any written communication as soon as reasonably practicable.

**4.4 Development Program Funding.** Par shall make the payments for Development Costs in accordance with Section B.10 of Exhibit B. If in any calendar year Advancis anticipates a Development Funding Gap or there is a Development Funding Gap, within its sole discretion, Advancis shall have the right (a) to continue to incur and self-fund the Development Costs for such calendar year and/or (b) to procure third party funding of such shortfall and/or (c) to modify or delay the Development Plan in order to adjust the amount or timing of funds needed thereunder to match the payments being made by Par pursuant to Exhibit B. Provided that Advancis shall use Commercially Reasonable Efforts to notify Par quarterly of the Development Costs incurred by Advancis in accordance with this Agreement as they are incurred during Term; nothing herein shall restrict Advancis's right to reasonably delay or withhold its invoicing of Development Costs incurred under this Agreement pursuant to the foregoing items (a), (b) and (c) of this Section 4.4. Any delay in the Development Plan pursuant to this Section 4.4 shall not be deemed a failure to exert Commercially Reasonable Efforts by Advancis. To the extent that there is a Development Funding Gap, such Development Funding Gap shall be reimbursed to Advancis out of Par's share of Operating Profits in accordance with Exhibit B.

**4.5 Development Program Reporting.**

**4.5.1.** Advancis shall provide Par at regularly scheduled meetings of the Development and Manufacturing Subcommittee with summary updates regarding the progress of the Development Program and Regulatory Approval process.

**4.5.2.** Advancis shall advise Par of any unforeseen material problems or delays encountered since the date of its last report in connection with the Development Program.

4.5.3. Advancis shall provide Par as soon as reasonably practicable with such other material information as Par may reasonably request in writing or through Advancis's Alliance Manager from time to time with respect to the status of the Development Program.

## ARTICLE V COMMERCIALIZATION ACTIVITIES

**5.1 Shared Responsibility and Control.** The Parties agree and acknowledge that both Parties shall share responsibility and control for Commercialization of the Products in the Territory in accordance with the terms of this Agreement and the Commercialization Plans. The Parties shall keep each other apprised of and consult with each other regarding their respective Commercialization activities for the Products on a regular basis through the Sales and Marketing Subcommittee and, to the extent appropriate, the Executive Committee.

### **5.2 Commercialization Plans.**

**5.2.1 Negotiation and Approval.** For each calendar year, the Sales and Marketing Subcommittee shall be responsible for preparing a detailed plan and budget for the Premarketing Program and the Commercialization of Products in the United States for submission to the Executive Committee (each, a "*Draft Plan*"). Each Draft Plan shall be reviewed by the Executive Committee, and the Executive Committee shall have the right to amend or revise each Draft Plan prior to approval thereof. A Draft Plan with any amendments or revisions as approved by the Executive Committee shall be a "*Commercialization Plan*." The initial Commercialization Plan shall be consistent with the Preliminary Commercialization Plan and shall address the matters specified in Exhibit C; provided, that if (a) it becomes impractical to pursue Commercialization of the Products on a "once-daily, 5-day therapy" basis (whether due to the results of the Phase III Studies or otherwise) or (b) if at any time prior to completion of the Phase III Studies the Operating Profits that the Parties may reasonably expect to receive are materially adversely affected by the entry into the market of one or more competing products, then the initial Commercialization Plan shall include such departures from the Preliminary Commercialization Plan and Exhibit C as are approved by the Executive Committee. Additionally, for purposes of clarity, the parties understand and agree that the number of Sales Representatives to be deployed has not as of the Effective Date been agreed and shall be addressed in the initial Commercialization Plan. The Finance Subcommittee shall assist the Sales and Marketing Subcommittee and the Executive Committee in the preparation of the budget portion of each Commercialization Plan.

**5.2.2** Beginning with the year 2005, on or before April 1 of each calendar year during the term, the Sales and Marketing Subcommittee shall commence preparation of an annual Draft Plan for the next succeeding calendar year. Each such proposed annual Draft Plan shall be submitted for approval by the Executive Committee on or before June 1 of such calendar year. The Executive Committee may adopt any proposed Draft Plan with or without modification. If the Executive Committee fails to adopt an annual Commercialization Plan prior to September 30 of a calendar year, then the Commercialization Plan then in effect shall remain in effect for the following until the adoption of a new Commercialization Plan. Notwithstanding the foregoing provisions, the first annual Draft Plan shall be prepared as follows: as soon as

practical after the Effective Date, the Sales and Marketing Subcommittee shall commence preparation of an annual Draft Plan for calendar year 2005 and shall submit such proposed annual Draft Plan for approval by the Executive Committee on or before December 1, 2004. Upon receipt of such proposed Draft Plan, and subject to Baseball Arbitration, the Executive Committee shall negotiate in good faith and take such other steps as may be necessary to adopt an initial Commercialization Plan as promptly as practicable.

**5.2.3 Conduct of Commercialization Efforts.** Each of the Parties shall use Commercially Reasonable Efforts to conduct its Commercialization efforts in accordance with the then-current Commercialization Plan. The Parties shall comply, and shall require all of their third party agents and contractors, if any, to comply, with all applicable laws in the conduct of their Commercialization activities hereunder. The Parties agree to Commercialize the Products only under the Product Trademarks, the names of the Parties and, if applicable, the Advancis Slogan. The foregoing notwithstanding, the Product Label may include the names of manufacturers or other parties to the extent required by Applicable Law.

**5.2.4 Co-Promotion.**

**5.2.4.1** Both Parties shall have the right to Promote the Products for sale in the Territory. All materials created or used for the Promotion of the Products, in any media, including all written, graphic, electronic, audio and video pieces and including journal advertisements, direct mail, direct to consumer advertising, internet postings and web sites, broadcast advertisements and giveaway items such as pens, cups, note pads and the like, and all Product packaging and labeling, are referred to as the "*Promotional Materials.*"

**5.2.4.2** Each Commercialization Plan shall allocate responsibility between the Parties for the development, creation and distribution of the Promotional Materials. The final forms of all Promotional Materials shall require the mutual approval of both Parties prior to their distribution or use. Advancis shall have responsibility for and sole control over any filings required to be made with the FDA in connection with the Promotional Materials and the Parties' Commercialization activities. In their Promotion of the Products, the Parties shall only utilize the Promotional Materials and shall not use promotional materials relating to any other product. Promotional Materials shall be allocated to each Party according to each Party's Detailing Requirements for the applicable period or as otherwise provided in the applicable Commercialization Plan.

**5.2.4.3** All Commercialization activities conducted by the Parties shall be consistent with the Promotional Materials so approved and the then-current Commercialization Plan.

**5.2.4.4** Advancis shall own all copyrights in the Promotional Materials. Par hereby assigns all right, title and interest in and to all copyrights in the Promotional Materials to Advancis. Par shall execute whatever reasonable additional documents Advancis deems necessary or appropriate to vest in Advancis such rights in and to the copyrights in Promotional Materials it creates or commissions. Par shall cause any third party engaged by Par to create, in whole or in part, any Promotional Materials to execute whatever assignments and other documents Advancis deems necessary or appropriate to vest in Advancis such copyrights in and



to the Promotional Materials. Par shall inform any such third party of the requirements of this Section 5.2.4.4 prior to engaging its services.

**5.2.4.5** All Promotional Materials shall bear the corporate names and logos/trademarks of each Party in substantially equal prominence and frequency. All Promotional Materials also shall bear one or more of the Product Trademarks and the Advancis Slogan, if applicable.

### **5.2.5 Distribution; Pricing.**

**5.2.5.1** Advancis hereby appoints Par as Advancis's sole distributor of the Products in the Territory. Accordingly, Par shall be solely responsible for the sale and distribution of the Products in the Territory under the Commercialization Plans, including (a) booking sales, (b) handling all returns, (c) handling all aspects of order processing, invoicing and collection of receivables, (d) collecting data regarding sales to hospitals and other end users, (e) monitoring inventory levels, and (f) warehousing. Par shall provide all such sales and distribution activities in accordance with the Commercialization Plans and shall store and distribute the Products in full compliance, and otherwise fully comply, with all applicable laws, including the requirements of the PDMA.

**5.2.5.2** Notwithstanding the foregoing provisions; (a) the Parties shall be jointly responsible for all pricing decisions, including decisions relating to customer allowances and credits, as well as any discounts and rebates; and (b) if Par, its Affiliates or their Marketing Distributors sell Products to a customer who also purchases other products or services from any such entity, Par agrees not to, and to require its Affiliates and their Marketing Distributors not to, discount, price or otherwise Promote Products in a manner that disadvantages Products in order to benefit sales or prices of other products or services offered for sale by Par, its Affiliates or their Marketing Distributors to such customers.

### **5.2.6 Product Sales Force; Deployment and Control.**

Each Party hereby agrees that it will hire, train, and deploy Sales Representatives comprising its Product Sales Force in such numbers as are agreed in the then-current Commercialization Plan and at such times with respect to each Product for the Targeted Prescribers to ensure compliance with all Detailing Requirements of such Commercialization Plan. Each Party shall have exclusive control over its own Product Sales Force; provided, however that each Party shall train its Product Sales Force in accordance with the training guidelines established by the Sales and Marketing Subcommittee. Each Party recognizes the importance of establishing its Product Sales Force in advance of the launch of the Products and agrees to use Commercially Reasonable Efforts to deploy its Product Sales Force at least one month prior to the first commercial launch of any Product. Nothing in this Agreement shall be construed to mean that any Sales Representatives of one Party are agents or employees of the other Party or under the direction or control of the other Party. Each Party shall have sole control over the terms and conditions of its Sales Representatives' hiring, employment and termination; provided however, that each Party shall cause its Product Sales Force to provide sales services in accordance with any guidelines or standards established by the Sales and Marketing Subcommittee. Each Party shall be solely responsible for compensating its own Sales Representatives, including paying salaries and

expenses, providing benefits, deducting taxes, and the like. Notwithstanding anything else to the contrary, each Party shall have the right to perform fifty percent (50%) of the Total Details set forth in the Commercialization Plan, and neither Party shall be required to perform more than sixty percent (60%) of the Total Details set forth in the Commercialization Plan without the written agreement of both Parties and neither Party shall perform less than forty percent (40%) of the Total Details set forth in the Commercialization Plan without the written agreement of both Parties. Subject to the preceding sentence, the Commercialization Plan shall set forth the percentage of the Total Details to be performed by each Party and to the extent that a Party is to perform more than fifty percent (50%) of the Total Details, the Commercialization Plan shall set forth the amount to be paid to such Party by the other Party to fairly compensate such Party for performing such excess Details based on Product Sales Force Costs of such Party.

**5.2.7 Detailing Reports.** Each Party shall provide the other Party with a report as soon as practicable but in no event later than forty-five (45) days following the end of each month setting forth, in such detail and form as the Parties shall agree, the number of Details made and the amount of Samples distributed by such Party's respective Sales Representatives in the United States during such month, provided, that the report for the final month in each calendar year shall be cumulative and reflect the number of Details made and Samples distributed by such Party's respective Sales Representatives in the United States during such calendar year.

**5.2.8 Premarketing and Promotion Costs.** As set forth in Exhibit B the parties shall equally share Premarketing Costs and Promotion Costs for all Products.

**5.2.9 Samples.** Following the first commercial launch of any Product and in support of each Party's Detailing and Promotional activities hereunder, Advancis shall provide Par with Samples in accordance with Section 8.2 and as required in the then-current Commercialization Plan. Samples shall be allocated between the Product Sales Force of each Party in accordance with the number of Details the respective field forces are required to undertake as set forth in the then-current Commercialization Plan. Advancis and Par shall use Samples strictly in accordance with the applicable Commercialization Plan and shall store and distribute such Samples in full compliance, and otherwise fully comply, with all applicable laws, including the requirements of the PDMA. Advancis and Par each will maintain those records required by the PDMA and all other laws with respect to the Samples allocated to each of them. Each of Advancis and Par shall be responsible for the filing of any reports required by the PDMA with respect to the Samples allocated to it. Each Party shall destroy any Samples not distributed by its Sales Representatives at such Party's sole expense.

**5.2.10 Healthcare Professional Inquiries.** The Sales and Marketing Subcommittee, working in conjunction with the other Subcommittees, shall develop and provide the Parties with written information and materials appropriate for distribution by the Parties' Sales Representatives to health care professionals and consumers relating to each FDA-approved use of the Products; provided that final forms of all such written information and materials shall be mutually approved by the Parties. Par shall promptly forward to Advancis any medical questions or inquiries Par receives from health care professionals or consumers relating to the Products which questions or inquiries require a response other than delivery of such pre-approved information or materials. The Sales and Marketing Subcommittee shall develop and

provide Advancis with such additional written information and materials as Advancis may request to allow Advancis' medical professionals to respond to medical questions or inquiries concerning all other matters relating to the Products in accordance with Advancis's policies and procedures for responding to unsolicited medical inquiry requests on off-label use.

### **5.3 Additional Parties to Commercialization Efforts.**

**5.3.1** Either Party may contract with third party vendors and contractors, such as contract sales organizations, in order to meet such Party's obligations under the then-current Commercialization Plan; provided that (i) such Party shall remain fully responsible for its compliance with all such obligations, and (ii) the contracting Party shall have obtained the prior written consent of the other Party (such consent not to be unreasonably withheld or delayed) to the terms and conditions on which any such third party vendors or contractors will provide their services. Subject to Section 5.2.6, if and to the extent that either Party notifies the other Party that such Party is unable to meet such Party's obligations under the then-current Commercialization Plan, the other Party shall have the option to increase its Commercialization activities so that the Parties, together, meet the aggregate targets specified in the then-current Commercialization Plan.

**5.3.2** The Parties anticipate that, in order to successfully implement the Commercialization Plans, it may be necessary or advisable to collaborate with an additional party that can provide material assistance to the Parties with respect to some or all of the items in the then-current Commercialization Plan at a level consistent with the efforts contemplated to be provided by the Parties, including, by way of example, a third party agreement to assume responsibility for the marketing and sale of a Product to a particular prescriber base for a given Indication. Notwithstanding the foregoing, to the extent the Parties do not enter into a further collaboration with any such third party, the Parties shall undertake their Commercialization efforts in accordance with the then-current Commercialization Plan, including all Detailing Requirements and related matters.

### **5.4 Trademarks.**

**5.4.1** It is the intent of the Parties that a new primary trademark shall be developed for use on and in connection with the Commercialization of Products in the Territory (the "*Principal Trademark*"). The Principal Trademark and any other related trademarks, logos, trade names, and similar source identifiers that are created or selected for use in connection with the Commercialization of the Products are referred to collectively as the "*Product Trademarks*." In addition, Advancis will develop and, from time to time, modify in its sole reasonable discretion, a slogan for use on and in connection with its products, including the Products (the "*Advancis Slogan*"). The Product Trademarks shall not include any trademarks, logos, trade names or similar source identifiers that (i) are owned or licensed by Advancis as of the Effective Date, including the names and marks ADVANCIS and PULSYS, the Advancis Slogan, any other marks created, acquired or licensed by Advancis at any time for use in connection with products other than the Products, and any marks consisting, in whole or in part, of such marks (the "*Advancis Marks*"); or (ii) are owned or licensed by Par as of the Effective Date, including the name and mark PAR, any marks consisting, in whole or in part, of such mark, and any other

marks created, acquired or licensed by Par at any time for use in connection with products other than the Products (collectively, the "*Par Marks*").

**5.4.2** The Product Trademarks each shall be selected by Advancis subject to consent of Par, such consent not to be unreasonably withheld or delayed. Advancis shall be the sole owner of all worldwide rights in the Product Trademarks. Advancis shall use Commercially Reasonable Efforts to search and clear rights to the Principal Trademark and to apply for, register and maintain a U.S. federal trademark registration for the Principal Trademark; provided that the costs (excluding legal fees) for such procurement and maintenance of such trademark registration shall be shared by the Parties as provided in the applicable Commercialization Plan and Financial Planning Schedule. Advancis shall have the sole right and responsibility to decide whether to seek or continue to seek or to maintain trademark rights and/or trademark applications/registrations for any other Product Trademarks or in any other country with respect to any Product Trademarks.

**5.4.3** During the Term, in furtherance of the purposes and subject to the terms and conditions of this Agreement, Advancis hereby grants Par the non-exclusive, non-transferable, non-sublicensable, limited right and license to use and display the Product Trademarks solely in connection with the Commercialization of the Products in the Territory in accordance with the terms of this Agreement and the Commercialization Plans and for no other purpose. Advancis represents and Par acknowledges that Advancis is granting Par rights only to the extent that Advancis has or acquires such rights.

**5.4.4** Except as otherwise specified in this Agreement, the Parties' Commercialization activities under the Product Trademarks shall be subject to the oversight and control of the Sales and Marketing Subcommittee. The Parties' respective representatives comprising the Sales and Marketing Subcommittee shall establish and maintain a high and uniform standard of quality for such Commercialization activities. The Parties shall use the Product Trademarks solely in accordance with the reasonable Trademark Usage Guidelines which shall be established by Advancis. Advancis may reasonably modify its Trademark Usage Guidelines at any time and from time to time, and any such modified guidelines shall become binding hereunder upon notice to Par. Par shall cooperate fully and in good faith with Advancis to preserve and protect the Product Trademarks.

**5.4.5** Par acknowledges the great value of the goodwill that is or will be associated with the Product Trademarks. Par agrees that it shall not assert any claim of ownership to any Product Trademarks or otherwise interfere with Advancis's sole and exclusive rights to the Product Trademarks. All goodwill from use of the Product Trademarks by Par shall inure to the benefit of Advancis, and Par shall not take any action in derogation of any of the rights of Advancis in the Product Trademarks. To protect and preserve the goodwill associated with the Product Trademarks, Par shall avoid deceptive, misleading or unethical practices that are or might be detrimental to the Products, Advancis or the public, and will refrain from publishing or employing any misleading or deceptive advertising. Par shall not, during the Term or after termination of this Agreement, register or attempt to register with any agency or in any jurisdiction any Product Trademark or any mark confusingly similar therewith or register any domain name comprised of a Product Trademark.

**5.4.6** Advancis acknowledges the great value of the goodwill that is or will be associated with the Par Marks. Advancis agrees that it shall not assert any claim of ownership to any Par Marks or otherwise interfere with Par's sole and exclusive rights to the Par Marks. All goodwill from use of the Par Marks shall inure to the benefit of Par, Advancis shall not take any action in derogation of any of the rights of Par in the Par Marks. To protect and preserve the goodwill associated with the Par Marks, Advancis shall avoid deceptive, misleading or unethical practices that are or might be detrimental to Par, or the public, and will refrain from publishing or employing any misleading or deceptive advertising. Advancis shall not, during the Term or after termination of this Agreement, use, register or attempt to register with any agency or in any jurisdiction any trademark or any mark confusingly similar with the Par Marks or register any domain name comprised of a Par Mark.

**5.4.7** Par acknowledges the great value of the goodwill that is or will be associated with the Advancis Marks. Par agrees that it shall not assert any claim of ownership to any Advancis Marks or otherwise interfere with Advancis' sole and exclusive rights to the Advancis Marks. Par shall not take any action in derogation of any of the rights of Advancis in the Advancis Marks. To protect and preserve the goodwill associated with the Advancis Marks, Par shall avoid deceptive, misleading or unethical practices that are or might be detrimental to Advancis, or the public, and will refrain from publishing or employing any misleading or deceptive advertising related to the Advancis Marks. Par shall not, during the Term or after termination of this Agreement, use, register or attempt to register with any agency or in any jurisdiction any trademark or any mark confusingly similar with the Advancis Marks or register any domain name comprised of an Advancis Mark.

**5.4.8** Each Party shall notify the Alliance Managers promptly upon learning of any actual, alleged or threatened infringement of any Product Trademark applicable to a Product in the Territory, or of any unfair trade practices, trade dress imitation, passing off of counterfeit goods, or like offenses in the Territory. Upon learning of such offenses from a Party regarding a Product Trademark, the Alliance Managers shall confer with the Parties regarding the defense of the Product Trademark; provided, that the decision whether and how to defend such Product Trademark shall rest with Advancis, and Advancis shall have the sole right to respond to and defend any such infringement or offense. To the extent Advancis elects to defend the Product Trademark, it shall use Commercially Reasonable Efforts to protect, defend and maintain the Product Trademark for use by the Parties in the Territory in connection with the Product. The Parties shall cooperate in good faith with respect to all Product Trademark enforcement actions hereunder, and each Party shall notify the other Party promptly of all substantive developments with respect to such Product Trademark enforcement actions, including all material filings, court papers and other related documents. Advancis also shall have the right to control settlement of any such infringement claim. The Parties shall share equally the cost and expense of any action under this Section 5.4.8.

**5.4.9** Each Party shall notify the Alliance Managers promptly upon learning of any third-party claim of infringement or similar claim alleged or brought against either Party relating to any Product Trademark. Upon learning of such claim, the Alliance Managers shall confer with the Parties regarding the appropriate response; provided, that the decision whether and how to defend against such claim shall rest with Advancis, and Advancis shall have the sole right to respond to and defend against any such claim. To the extent Advancis elects to defend

against such claim, it shall use Commercially Reasonable Efforts to do so. The Parties shall cooperate in good faith with respect to all such actions hereunder, and each Party shall notify the other Party promptly of all substantive developments with respect to such actions, including all material filings, court papers and other related documents. Advancis also shall have the right to control settlement of any such claims. Advancis shall solely bear the cost and expense of any such action or claim including any damages payable to any Third Party.

## **ARTICLE VI PAYMENTS**

**6.1 Upfront Payments.** In consideration for the execution and delivery of this Agreement by Advancis, Par shall pay Advancis a fully-earned, non-refundable, non-creditable license fee in the amount of Five Million U.S. Dollars (US\$5,000,000) by wire transfer of immediately available funds upon execution and delivery of this Agreement.

**6.2 Collaboration Payments.** Par shall pay Advancis collaboration payments (collectively, "*Collaboration Payments*") based on the sale of Products by Par (or its Affiliates or sublicensees, as applicable) in an amount equal to fifty percent (50%) of Operating Profits, as set forth in the Financial Planning Schedule.

**6.3** Par shall make payments to Advancis in the amounts and on the dates set forth in Section B.10 of Exhibit B.

## **ARTICLE VII INTELLECTUAL PROPERTY RIGHTS AND LICENSES**

### **7.1 License Grant.**

**7.1.1** Subject to the terms and conditions of this Agreement including Advancis's rights pursuant to Sections 5.1 and 5.2, Advancis hereby grants to Par an exclusive, nontransferable right and license, solely during the Term (except as otherwise provided in Section 12.3) and in the Territory, under all Advancis Patent Rights, Advancis Know-How and Program Developments, in each case solely as embodied in the Products, to Promote, Detail, offer to sell, sell and have sold in the Territory the Products purchased by Par from Advancis for all approved human therapeutic uses.

**7.1.2** Par shall not sell, distribute or transfer any Product to any Person that, to Par's knowledge, is using any Product outside of the Territory or is selling or transferring any Product to a Person who is using such Product outside of the Territory.

**7.1.3** Par agrees that during the Term it will use Advancis Patent Rights, Advancis Know-How and Program Developments owned by Advancis only as explicitly provided under this Agreement, in each case, in accordance with the terms and conditions of this Agreement. Moreover, Par expressly acknowledges and agrees that the only licenses granted under this Agreement are the licenses expressly granted under this Agreement and that there shall be no implied license or license by estoppel.

**7.2 Ownership of Intellectual Property.** Par hereby acknowledges and agrees that, as between Par and Advancis, (a) Advancis owns and shall continue at all times to own all right, title and interest in and to the Advancis Patent Rights and Advancis Know-How, including all intellectual property rights appurtenant thereto, and (b) Advancis shall own all right, title and interest in and to all Program Developments made by Advancis employees or Advancis's third party contractors or made jointly with Par, including all intellectual property rights appurtenant thereto. To the extent that Par employees are the sole inventors of any Program Developments, Par shall be the sole owner of such Program Developments, provided that Par gives written notice to Advancis of Par's assertion of sole inventorship within a reasonable time frame following the invention or discovery of such Program Development. Par hereby grants to Advancis a limited non-exclusive license under all of its right, title and interest, if any, in and to all such Program Developments to make, have made, use, import, offer for sale and sell Products during the Term. To the extent necessary to assign joint inventions, Par shall enter into and execute all reasonable and appropriate assignments, transfers and other agreements, and enter into all agreements with its employees, contractors and Affiliates, that are necessary or appropriate to ensure the assignment of such Program Developments to Advancis. The Parties shall cooperate fully with each other with respect to patent filing, prosecution, and enforcement of all such Program Developments, including cooperating in obtaining the execution of any necessary documents by its employees and other persons under its control.

**7.3 Non-Use of Trademarks.** Except as set forth explicitly in this Agreement, neither Party shall have the right to use the trademarks, trade names or logos of the other Party, nor any adaptation thereof, nor the names of any employees or consultants of the other Party, without the prior written consent of the other Party in each instance, except that either Party may use the other Party's name in its general list of collaborators and either party may use the other Party's name to the extent required by applicable law, including pursuant to the Securities Act of 1933, as amended, and the rules and regulations thereunder.

## **ARTICLE VIII MANUFACTURE AND SUPPLY**

**8.1 Clinical Supplies.** Advancis shall manufacture or cause to be manufactured all Clinical Supplies of Product for the Development Program, including the completion of pre-clinical work and human clinical trials with respect to the Indications for the Products in the Territory. As soon as practicable after the Effective Date Advancis shall negotiate and enter into one or more manufacturing and supply agreements with one or more third party contract manufacturers for the manufacture, supply and quality control of such Clinical Supplies of the Products. Advancis's choice of such third party contract manufacturer(s), and the terms and conditions of such manufacturing and supply agreement(s), shall be subject to reasonable prior review by the Development and Manufacturing Subcommittee (which includes the reasonable input of Par). If a vote of the Development and Manufacturing Subcommittee disapproves of the third party contract manufacturer(s) or the proposed manufacturing and supply agreement for such Clinical Supplies, such dispute shall be referred to the Executive Committee for review and discussion, provided that all decision-making authority with respect thereto shall remain with Advancis, which may enter into any such manufacturing and supply agreement over the

objections of the Development and Manufacturing Subcommittee and/or the Executive Committee.

**8.2 Commercial Supplies.** Advancis shall be responsible for establishing a commercial manufacturing process and for manufacturing or causing to be manufactured Commercial Supplies of the Products, at the scale and in the amounts required to carry out the then-current Commercialization Plan. Advancis shall negotiate and enter into one or more manufacturing and supply agreements with one or more third party contract manufacturers for the manufacture, supply and quality control of such Commercial Supplies of the Products as soon as practicable after execution and delivery of this Agreement. Advancis's choice of such third party contract manufacturer(s), and the terms and conditions of such manufacturing and supply agreement(s) shall be subject to reasonable prior review by the Development and Manufacturing Subcommittee (which includes the the reasonable input of Par). If a vote of the Development and Manufacturing Subcommittee disapproves of the third party contract manufacturer(s) or the proposed manufacturing and supply agreement for such Commercial Supplies, such dispute shall be referred to the Executive Committee for review and discussion; provided that all decision-making authority with respect thereto shall remain with Advancis, which may enter into any such manufacturing and supply agreement over the objections of the Development and Manufacturing Subcommittee and/or the Executive Committee.

**8.3 Supply and Distribution Terms.** The detailed terms of Advancis's supply to Par of the Commercial Supplies shall be governed by a supply and distribution agreement between the Parties (the "*Supply Agreement*"), which the Parties agree to negotiate in good faith and use their Commercially Reasonable Efforts to enter into as soon as practicable after the Effective Date on terms substantially the same as those received from the third-party Product manufacturer, except that the parties understand and agree that any allocations of product liability as between the parties has not been agreed upon. The Supply Agreement shall include a provision that the price for Product to be paid by Par to Advancis shall be equal to the aggregate of (i) price paid for Product by Advancis to the Third Party manufacturer, and (ii) other amounts which Advancis is obligated to pay in relationship to the Product (including, e.g. shipping of the Product) under a supply agreement for Product with a Third Party manufacturer. In the event Advancis is unable to supply adequate Commercial Supplies, Par shall have the right, subject and pursuant to the Supply Agreement, to obtain such Commercial Supplies in any reasonable fashion as more fully described in the Supply Agreement. Notwithstanding anything to the contrary herein, if the Parties fail to agree on the terms of the Supply Agreement within 180 days after the date hereof, either party may by written notice cause the disputed provisions to be subject to resolution by arbitration in accordance with Section 17.2.2.

## **ARTICLE IX REPORTS AND RECORDS**

**9.1** Each of the Parties shall keep and maintain, and shall require its Affiliates to keep and maintain, complete and accurate books in respect of its respective obligations and activities under this Agreement, including such activities for which payment may be required, in accordance with applicable accounting principles consistently applied (including generally accepted accounting principles) and in accordance with applicable law. Each Party and its



Affiliates shall maintain records in sufficient detail and in good scientific manner appropriate for patent and FDA purposes and so as to properly reflect all work done and results achieved in the performance of the Development Program, the Premarketing Program, and Commercialization of the Products. Such records may include, as applicable, books, records, reports, formulae, research notes, charts, graphs, comments, computations, analyses, recordings, photographs, computer programs and documentation thereof, samples of materials and graphic or written data generated in connection with the Development Program and the Premarketing Program, and Commercialization of the Products, including any data required to be maintained pursuant to applicable governmental regulations. The Parties and their Affiliates shall retain such records for five years after the period to which such records relate, or for such longer or shorter period as the Parties shall mutually determine.

## **ARTICLE X CONFIDENTIAL AND TECHNICAL INFORMATION**

**10.1 Treatment of Confidential Information.** Each Party agrees to retain in strict confidence and not to disclose, divulge or otherwise communicate to any other person or entity any Confidential Information of the other Party, whether received prior to or after the date hereof, and further agrees not to use any such Confidential Information for any purpose, except pursuant to, and in order to carry out, the terms and objectives of this Agreement, except that each Party may disclose Confidential Information of the other Party to the officers, directors, employees, agents, accountants, attorneys, consultants, subcontractors or other representatives of the receiving Party or its Affiliates (the “*Representatives*”), who, in each case, (a) need to know such Confidential Information for purposes of the implementation and performance by the receiving Party of this Agreement and (b) will use the Confidential Information only for such limited purposes. Each Party hereby agrees to use at least the same standard of care in complying with its confidentiality obligations hereunder as it uses to protect its own Confidential Information of comparable sensitivity and to exercise reasonable precautions to prevent and restrain the unauthorized disclosure of such Confidential Information by any of its Representatives. Each Party warrants that each of its Representatives to whom any Confidential Information is revealed shall previously have been informed of the confidential nature of the Confidential Information and shall have agreed to maintain its confidentiality under terms no less restrictive than those set forth in this Article X. Without limiting the generality of any of the foregoing, the parties agree not to make any disclosure of Confidential Information that would be reasonably likely to impair the Parties’ ability to obtain U.S. or foreign patents on any patentable invention or discovery described or otherwise embodied in such Confidential Information. The Confidential Information of each Party includes information from Third Parties disclosed by one Party to this Agreement to the other Party to this Agreement.

### **10.2 Release from Restrictions.**

**10.2.1** The provisions of Section 10.1 shall not apply to any Confidential Information disclosed hereunder to the extent that such Confidential Information is required to be disclosed by the receiving Party to defend or prosecute litigation or to comply with applicable laws or regulations, including filing an Information Disclosure Statement with the U.S. Patent and Trademark Office or any other patent office, or pursuant to an order of a court or regulatory

agency, provided that the receiving Party shall provide prior written notice of such disclosure to the other Party and shall take actions as are reasonable and lawful to avoid and/or minimize the degree of such disclosure. To the extent, if any, that a Party concludes in good faith that it is required by applicable laws or regulations to file or register this Agreement or a notification thereof with any governmental authority, including the U.S. Securities and Exchange Commission, such Party may do so, and the other Party shall cooperate in such filing or notification and shall execute all documents reasonably required in connection therewith. In such situation, the filing Party shall request confidential treatment of sensitive provisions of the Agreement, to the extent permitted by law. The Parties shall promptly inform each other as to the activities or inquiries of any such governmental authority relating to this Agreement, and shall cooperate to respond to any request for further information therefrom.

**10.2.2** A Party may disclose this Agreement to a Third Party in connection with or in conjunction with a proposed merger, consolidation, sale of assets that include those related to this Agreement, an assignment of this Agreement or loan financing, raising of capital, or sale of securities, provided that the disclosing Party obtains an agreement for confidential treatment thereof, except in the case where after reasonable efforts such Party is unable to obtain such confidential treatment.

**10.3 No Implied Rights.** Except as otherwise set forth in this Agreement, nothing herein shall be construed as giving either Party any right, title, interest in or ownership of the Confidential Information of the other Party. For the purposes of this Agreement, specific information disclosed as part of Confidential Information shall not be deemed to be in the public domain or in the prior possession of the receiving Party merely because it is embraced by more general information in the public domain or by more general information in the prior possession of the receiving Party.

**10.4 Survival of Confidentiality Obligations.** The confidentiality obligations of the Parties contained in this Article X shall remain binding on both Parties during the Term and for a period of five (5) years after the termination of this Agreement, regardless of the cause of such termination. The Parties acknowledge that any breach of this Article X will constitute irreparable harm, and that the non-breaching Party shall be entitled to specific performance or injunctive relief to enforce this Article X in addition to whatever remedies such Party may otherwise be entitled to at law or in equity.

**10.5 Superseding Prior Confidentiality Agreement.** The provisions of this Article X shall supersede the Confidentiality Agreement between the Parties dated July 8, 2003 with respect to the subject matter hereof, and shall establish the sole obligations of confidentiality and nonuse of Confidential Information received by a Party prior to or after the Effective Date.

**10.6 Tax Treatment.** If a Party, or any Affiliate or Representative of a Party, receives a statement made by or on behalf of the other Party, or any Affiliate or Representative of the other Party, as to the tax consequences to the other Party or its Affiliate of any of the arrangements, agreements, or transactions provided for in this Agreement, then the receiving Party may disclose as it wishes the tax treatment and tax structure of such arrangement, agreement, or transaction, including any tax opinions or tax analyses related thereto.

**ARTICLE XI**  
**PATENT PROSECUTION AND INFRINGEMENT**

**11.1 Patent Prosecution and Maintenance.**

**11.1.1** Par shall inform Advancis promptly in reasonable detail of any Program Developments by Par or any of its Affiliates or agents.

**11.1.2** As between Advancis and Par, Advancis shall have the sole right and responsibility to decide whether to seek or continue to seek or to maintain patent protection in any country with respect to any Advancis Patent Rights, Advancis Know-How and Program Developments owned by or licensed to Advancis, and whether to file for, procure, maintain and enforce Patent Rights in the Territory with respect to any Advancis Patent Rights and Program Developments owned by or licensed to Advancis.

**11.2 Infringement.**

**11.2.1** Par and Advancis shall inform each other promptly in writing of any alleged or suspected infringement by a Third Party of any of Advancis Patent Rights, Advancis Know-How or Program Developments, and of any available evidence thereof.

**11.2.2** Subject to Sections 11.2.3 and 11.2.4, Advancis may, at its sole option and expense, prosecute the infringement of any Advancis Patent Rights, Advancis Know-How or Program Developments.

**11.2.3** In the event that a Third Party infringes Advancis Patent Rights, Advancis Know-How or Program Developments owned by Advancis by manufacture, sale or use of a Product in the Territory (a "*Product Infringement*"), then the Parties shall discuss whether or not to institute an infringement action with respect to such Product Infringement. If the Parties agree to institute such a suit, then Advancis shall institute and control such suit including the settlement or compromise thereof. Par shall, at the request of Advancis, provide reasonable cooperation and, to the extent possible, have its employees testify when requested and make available relevant records, papers, information, Samples, specimens and the like. Advancis may join Par as a party, and Par shall execute all papers and perform such acts as may be reasonably required. The cost and expense of such suit shall be shared by the Parties equally. Any royalties, payments, damages, expense, fees or other awards (collectively, "*Damages*"), received by Advancis and/or Par as a result of such suit, whether through judgment or settlement, shall first be used to reimburse each Party for its expenses associated with such infringement suit and then any remainder shall be shared by the Parties equally, with such share of the Damages to be paid to the other party, as applicable, as soon as practicable upon receipt of the Damages.

**11.2.4** In the event that only Advancis does not agree to institute a suit against a Product Infringement pursuant to Section 11.2.3 within one-hundred and eighty days of being notified of such alleged or suspected infringement, Par may, at its option and expense prosecute such infringement of any Advancis Patent Rights, Advancis Know-How or Program Developments owned by Advancis, provided that Par can demonstrate through any industry recognized survey that such sales of Product by the alleged or suspected infringer in the Territory exceeds 12.5%, on a unit sales basis, of the sales in the Territory of the Product by Par during the

most recently completed two consecutive calendar quarters and Par obtains a written opinion from an outside patent counsel reasonably acceptable to Par that such infringement exists. However, Par shall not prosecute such infringement if Advancis chooses to negotiate with Par a mutually agreeable equitable adjustment to Exhibit B. Such negotiation shall be conducted between the Advancis and Par designees of the Executive Committee, and if agreement cannot be reached, such equitable adjustment will be determined in accordance with the dispute resolution process set forth in Section 17.2.2 herein. In any such infringement suit Par may institute to enforce Advancis Patent Rights, Advancis Know-How or Program Developments owned by Advancis, Advancis shall, at the request and expense of Par, provide reasonable cooperation and, to the extent possible, have its employees testify when requested and make available relevant records, papers, information, Samples, specimens and the like. Par may join Advancis as a party, and Advancis shall execute all papers and perform such acts as may be reasonably required, at the expense of Par. Par shall bear all the cost and expense of such suit and Par shall retain all payment, costs and damages received as a result thereof, whether by judgment, settlement compromise or otherwise Par shall not have the right to settle or compromise such action or take any steps that adversely affect the scope, validity, enforceability or ownership of Advancis Patent Rights or Advancis Know-How without the written consent of Advancis.

**11.2.5** In the event that only Par does not agree to institute suit against a Product Infringement pursuant to Section 11.2.3 within one-hundred and eighty days of being notified of such alleged or suspected infringement, then Advancis shall have the right to institute such an infringement suit at its cost and expense and to retain all payment, costs and damages received as a result thereof, whether by judgment, settlement compromise or otherwise.

**11.2.6** In the event that a declaratory judgment action alleging invalidity or non-infringement of any Advancis Patent Rights, Advancis Know-How or Program Developments shall be brought against Advancis and/or Par, Advancis, at its option, shall have the right, within sixty (60) days after commencement of such action, to take over the sole defense of the action at its own expense. In the event that Advancis does not so elect to take over the sole defense of the action at its own expense, Par shall be free to proceed and solely control such defense. To the extent that any Damages become payable to any Third Party as a result of such action, whether through judgment or settlement, the Parties shall bear such Damages equally, and shall contribute such share as promptly as practicable. Any Damages received by Advancis and/or Par as a result of such action, whether through judgment or settlement, shall first be used to reimburse each Party for its expenses associated with such infringement suit not otherwise reimbursed and then any remainder shall be shared by the Parties equally, with such share of the Damages to be paid to the other party, as applicable, as soon as practicable upon receipt of the Damages.

**11.2.7** In the event that a third party institutes any suit against Par and/or Advancis for patent infringement involving the Products, the Party sued shall promptly notify the other Party in writing. Advancis shall assume the defense of such suit, provided, however, that if Par is also a defendant in such action and Par shall have reasonably concluded that there may be legal defenses available to it that are different from or additional to those available to Advancis, Par shall have the right to select separate counsel to participate in such legal defenses on Par's behalf. The Parties shall share the cost and expense of such defense equally. Each Party shall, at

the other's request, provide to it reasonable assistance and cooperation with respect to any such suit. To the extent that any Damages become payable to any third party as a result of such action, whether through judgment or settlement, the Parties shall bear such Damages equally, and shall contribute such share as promptly as practicable. Any Damages received by Advancis and/or Par as a result of such action, whether through judgment or settlement, shall first be used to reimburse each Party for its expenses associated with such infringement suit not otherwise reimbursed and then any remainder shall be shared by the Parties equally, with such share of the Damages to be paid to the other party, as applicable, as soon as practicable upon receipt of the Damages.

**11.2.8** If either Party becomes aware of a patent or patent application that, when issued, might provide a basis for a Third Party argument that its valid rights are being infringed by the manufacture, use or sale of the Products hereunder, then such Party shall promptly inform the other Party of such patent or patent application, and the Parties shall cooperate with each other so that each Party can determine whether valid rights of a third party are likely to be infringed by the manufacture, use or sale of the Products hereunder.

**11.2.9** If either Party believes that a license from a third party is necessary to avoid infringement of patents of the third party, the Executive Committee shall: 1) determine whether or not to seek such a license, 2) appoint a negotiator to negotiate the terms of such a license, 3) determine whether or not to enter into such a license as negotiated by the negotiator, and 4) determine how the expenses of such a license shall be borne by the Parties. If the Executive Committee cannot agree with regard to any responsibility set forth in the preceding sentence, such issue shall be determined by arbitration in accordance with Section 17.2.2.

## **ARTICLE XII TERMINATION**

**12.1 Term.** The term of this Agreement shall commence upon the Effective Date and shall end on the later of (a) the date upon which there is no Valid Claim infringed by a Product in the Territory or (ii) the date which is fifteen (15) years from the date of first commercial sale of any Product, unless earlier terminated in accordance with Section 12.2, provided, however, that either Party may elect to extend the term for an additional period of five (5) years by giving written notice of such extension to the other Party no later than 270 days prior to such fifteen-year anniversary, unless the Party receiving such notice of extension objects to such extension by written notice to the Party seeking such extension within 90 days after receiving such notice of extension (such 15-year period, to the extent so extended (if any) and subject in all cases to earlier termination (if any), being referred to herein as the "**Term**").

**12.2 Termination Events.** In the event of (a) a material breach under this Agreement by a Party, whether or not such material breach is specifically described as such in this Agreement; (b) a Party becoming insolvent, or the commencement against a Party, of any case or proceeding under any bankruptcy, reorganization, insolvency or moratorium law, or any other law or laws for the relief of debtors, or the appointment of any receiver, trustee or assignee to take possession of the properties of such Party, unless such appointment is set aside or withdraws or ceases to be in effect, within sixty (60) days after its commencement or appointment; (c) the

liquidation or dissolution of a Party; or (d) the cessation of all or substantially all of a Party's business operations (in each case, such Party being referred to as the "*Defaulting Party*"), then the other Party (the "*Non-Defaulting Party*") shall have the right to terminate this Agreement (including all licenses granted hereunder) upon thirty (30) days written notice to the Defaulting Party, with such termination to become effective automatically upon expiration of said thirty (30) day period, unless within said thirty (30) day period the Defaulting Party shall have cured such breach, if such breach is reasonably susceptible to cure in such thirty (30) day period; provided that, if such breach is not reasonably susceptible to cure in such thirty (30) day period, then the Non-Defaulting Party shall not have the right to terminate hereunder in the event that the Defaulting Party shall have commenced to cure such breach and shall diligently be pursuing such cure; further provided, that the notice and cure period for breaches arising out of the failure to pay any obligations hereunder shall be limited to fifteen (15) days.

**12.3 Effect of Termination of Agreement.** Upon the expiration or termination of the Term in accordance with Section 4.2.2, Section 4.2.4, Section 12.1 or Section 12.2 for any reason: (a) (except to the extent required pursuant to clause (b) of this Section 12.3) all rights and licenses granted to Par pursuant to this Agreement shall automatically and immediately terminate and Par immediately shall discontinue Commercialization of Product and all use of the Product Trademarks (and any word or design confusingly similar thereto) the Advancis Know-How, Advancis Patent Rights and Program Developments owned by Advancis; all worldwide rights in the Product Trademarks and the goodwill related thereto shall remain the sole and exclusive property of Advancis; (b) solely for a termination pursuant to Section 12.2 with respect to which Par is the Non-Defaulting Party, and solely to the extent permitted by applicable law, Par shall have the right to sell any Products on hand at the date of termination, provided that all Collaboration Payments shall be paid and reports made to Advancis with respect to such Products in accordance with this Agreement; (c) except as provided in connection with the foregoing provision 12.3(b), Par promptly shall deliver to Advancis all Promotional Materials and any other materials bearing the Product Trademarks and instruments used for the purposes of affixing or displaying the Product Trademarks (to the extent that such Promotional Materials or other Materials were paid for by Par and were for use by Par, to the extent that they are thereafter used by Advancis, Advancis shall reimburse Par for the cost of such Promotional Materials or Materials); (d) Subject to Section 4.2.2.3 Par shall pay within thirty (30) days after such termination: (i) all accrued and unpaid amounts due to Advancis in accordance with the terms of this Agreement, including any unpaid Development Costs due under Section B.10 of Exhibit B and any unpaid Collaboration Payments with respect to all Products sold; and (ii) any other amounts that will become due to Advancis through or after the effective date of such termination; and (d) each Party shall return to the other Party, or destroy, at the other Party's request, all Confidential Information of the other Party. Except with respect to any termination of this Agreement pursuant to Section 4.2.1 (for which Section 4.2.2.2 shall apply) or pursuant to Section 12.2 with respect to which Par is the Non-Defaulting Party, on the date of termination, if there is a Development Funding Gap, within thirty (30) days thereafter Par shall pay to Advancis the lesser of the Development Funding Gap or an amount such that the aggregate of such amount and the amounts previously paid under Section B.10 of Exhibit B equals twenty eight million dollars (\$28,000,000.00).

**12.4 Survival.** In addition to all rights that have accrued as of the date of termination, the following provisions shall survive the termination of this Agreement for whatever reason:

Articles X, XIII, XV, XVII, and XVIII, and Sections 4.2.2.3, 5.4.2, 5.4.5, 12.3, 12.4, and 12.5. In addition, any other provision required to interpret and enforce the Parties' rights and obligations under this Agreement shall also survive, but only to the extent required for the observation and performance of the aforementioned surviving rights or portions of this Agreement.

**12.5 Remedies.** Upon the occurrence of any event set forth in Section 12.2 or any other breach of any provision of this Agreement, in addition to the termination rights or other rights set forth herein, each Party shall have all other rights and remedies at law or in equity to enforce this Agreement.

### **ARTICLE XIII INDEMNIFICATION**

**13.1 Indemnification by Par.** Par shall at all times during the term of this Agreement and thereafter, indemnify, defend and hold Advancis, its officers, directors, employees and agents and Affiliates, and the successors and assigns of the foregoing ("*Advancis Indemnified Parties*"), harmless from and against all expenses, damages, costs and liabilities of any kind whatsoever, including legal expenses and reasonable attorneys' fees as a result of a Third Party claim, suit, or cause of action (collectively, "*Losses*"), arising out of the material breach by Par of any representation, warranty or obligation of Par hereunder, or by a failure of Par to comply with all applicable laws, or the negligence or willful misconduct of Par, except for Losses that arise solely out of the gross negligence or intentional misconduct or illegal act of Advancis Indemnified Parties or to the extent Advancis is obligated to indemnify Par under Section 13.2.

**13.2 Indemnification by Advancis.** Advancis shall at all times during the term of this Agreement and thereafter, indemnify, defend and hold Par, its officers, directors, employees and agents and Affiliates, and the successors and assigns of the foregoing ("*Par Indemnified Parties*"), harmless against all Losses arising out of the material breach by Advancis of any representation, warranty or obligation of Advancis hereunder, or by a failure of Advancis to comply with all applicable laws, or the negligence or willful misconduct of Advancis, except for Losses that arise solely out of the gross negligence or intentional misconduct or illegal act of Par Indemnified Parties or to the extent Par is obligated to indemnify Advancis under Section 13.1.

**13.3 Conditions to Indemnification for Third Party Claims.** A Party that intends to claim indemnification under this Article XIII (the "*Indemnitee*") shall promptly notify the Indemnifying Party (the "*Indemnitor*") of any Losses in respect of which the Indemnitee intends to claim such indemnification, and the Indemnitor shall assume the defense thereof with counsel mutually satisfactory to the Parties, whether or not the underlying third party claim is rightfully brought. In addition to counsel provided by the Indemnitor, an Indemnitee shall have the right to retain its own counsel at its own cost in such proceedings. The indemnity agreement in this Article shall not apply to amounts paid in settlement of any loss, claim, damage, liability or action if such settlement is effected without the consent of the Indemnitor, which consent shall not be withheld or delayed unreasonably. The failure to deliver notice to the Indemnitor within a reasonable time after the Indemnitee has knowledge of any Losses, if prejudicial to the Indemnitor's ability to defend such action, shall relieve the Indemnitor of any liability to the

Indemnitee under this Article. At the Indemnitor's request, the Indemnitee, and its employees and agents, shall cooperate fully with the Indemnitor and its legal representatives in the investigation and defense of any third-party action, claim or liability covered by this indemnification and provide full information with respect thereto. The Indemnitor shall not settle or compromise any such third party claim without the written consent of the Indemnitee, which consent shall not be unreasonably withheld, but such consent shall not be required if the settlement or compromise involves only the payment of monies and the Indemnitee obtains a complete release thereunder.

**13.4 Indemnification for Infringement Claims.** The provisions of this Article XIII shall supplement the terms of Section 11.2 with respect to third-party patent infringement claims. In the event of a conflict between this Article XIII and Section 11.2, the terms of Section 11.2 shall control.

#### **ARTICLE XIV REPRESENTATIONS AND WARRANTIES**

**14.1 Legal Authority.** Each Party represents and warrants to the other as follows: (a) Such Party it has the legal power, authority and right to enter into this Agreement and to perform its respective obligations set forth herein; and (b) this Agreement has been duly executed and delivered by such Party and constitutes the valid and binding obligation of such Party, enforceable against such Party in accordance with its terms, except as enforceability may be limited by bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to or affecting creditors' rights generally and by general equitable principles.

**14.2 No Conflicts.** Each Party represents or warrants that as of the date of this Agreement it is not a party to any agreement or arrangement with any third party or under any obligation or restriction, including pursuant to its corporate charter, bylaws or comparable governing documents, which in any way limits or conflicts with its entering into this Agreement or its ability to fulfill any of its obligations under this Agreement. Additionally, Advancis represents and warrants that the Products that are the subject of the development efforts under the Development plan do not and shall not meet the test described in Exhibit A.

#### **ARTICLE XV LIMITATION OF LIABILITY**

**15.1 Limitation of Damages.** EXCEPT TO THE EXTENT BREACHES OF ARTICLE VII (INTELLECTUAL PROPERTY RIGHTS AND LICENSES) OR ARTICLE X (CONFIDENTIAL INFORMATION) REQUIRE PAYMENT OF SUCH DAMAGES TO A THIRD PARTY OR THAT AMOUNTS ARE PAYABLE TO A THIRD PARTY UNDER ARTICLE XIII, NEITHER PARTY NOR ANY OF ITS REPRESENTATIVES OR AFFILIATES SHALL BE LIABLE TO THE OTHER PARTY FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY KIND, INCLUDING ECONOMIC DAMAGE OR INJURY TO PROPERTY AND LOST PROFITS (EXCEPT TO THE EXTENT OF ACCRUED COLLABORATION PAYMENTS), REGARDLESS OF WHETHER SUCH PARTY SHALL BE ADVISED, SHALL HAVE OTHER REASON



TO KNOW OR IN FACT SHALL KNOW OF THE POSSIBILITY OF THE FOREGOING.

**15.2 No Implied Warranties by Advancis.** EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, ADVANCIS AND ITS REPRESENTATIVES AND AFFILIATES MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING (A) REPRESENTATIONS AND WARRANTIES REGARDING THE PRODUCTS, THE ADVANCIS PATENTS, THE ADVANCIS KNOW-HOW OR ANY TECHNOLOGY RELATED THERETO, THE ADVANCIS MARKS OR THE PRODUCT TRADEMARKS AND (B) ALL WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OF PATENT RIGHTS CLAIMS, ISSUED OR PENDING, ALL OF WHICH ARE HEREBY DISCLAIMED.

**15.3 No Implied Warranties by Par.** EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, PAR AND ITS REPRESENTATIVES AND AFFILIATES MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES REGARDING THE PRODUCTS, ANY INTELLECTUAL PROPERTY OR TECHNOLOGY RELATED THERETO, OR WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT AND FITNESS FOR A PARTICULAR PURPOSE, ALL OF WHICH ARE HEREBY DISCLAIMED.

## ARTICLE XVI ADVERSE EVENTS; INSURANCE

**16.1 Adverse Events and Recall.** Each Party shall give the other immediate notice, which shall be promptly confirmed in writing, of any occurrence that involves (i) any material complaint about the safety or effectiveness of any Product, including a claim of death or injury; and (ii) any other matter arising out of this Agreement that must be reported to a governmental authority. If either Party believes it may be necessary or desirable to conduct a recall, field correction, market withdrawal, stock recovery or other similar action with respect to any Product sold under this Agreement (a "*Recall*"), the Parties shall promptly consult with each other as to how best to proceed, it being understood and agreed that the final decision as to any Recall of any Product shall be made by the Parties jointly; provided, however, that neither Party shall be prohibited hereunder from taking any action that it is required to take under applicable law. The cost of any Recall shall be shared equally by the Parties, except that any Recall required because of a negligent or illegal act or omission in the handling, storage or distribution of Product by Par shall be at Par's sole expense.

**16.2 Insurance by Par.** Prior to the first sale or use in humans, whichever is earlier, of a Product (excluding any such sale or use by Advancis), Par shall obtain and carry in full force and effect commercial, general liability insurance, including product liability and errors and omissions insurance, which shall protect Par and Advancis with respect to events covered by Section 13.1 above. Such insurance (a) shall be written by a reputable insurance company

authorized to do business in the State of Maryland; (b) shall list Advancis as an additional named insured thereunder; (c) shall be endorsed to include product liability coverage; and (d) shall require not less than thirty (30) days written notice to be given to Advancis prior to any cancellation or materials change thereof. The limits of such insurance shall not be less than the amounts reasonably agreed to by the parties, which shall be consistent with industry norms and customs. Par shall promptly provide Advancis with Certificates of Insurance evidencing the same and shall not during the Term materially decrease such coverage or cancel such insurance without written approval from Advancis.

**16.3 Insurance by Advancis.** Prior to the first sale or use in humans, whichever is earlier, of a Product (excluding any such sale or use by Par), Advancis shall obtain and carry in full force and effect commercial, general liability insurance, including product liability and errors and omissions insurance, which shall protect Par and Advancis with respect to events covered by Sections 13.2 above. Such insurance (a) shall be written by a reputable insurance company authorized to do business in the State of New Jersey; (b) shall list Par as an additional named insured thereunder, (c) shall be endorsed to include product liability coverage; and (d) shall require not less than thirty (30) days written notice to be given to Par prior to any cancellation or material change thereof. The limits of such insurance shall not be less than the amounts reasonably agreed to by the parties, which shall be consistent with industry norms and customs. Advancis shall promptly provide Par with Certificates of Insurance evidencing the same and shall not during the Term materially decrease such coverage or cancel such insurance without written approval from Par.

## **ARTICLE XVII DISPUTE RESOLUTION**

**17.1 Good Faith Negotiations.** In the event of any dispute or disagreement between the Parties as to the interpretation of any provision of this Agreement or the performance of obligations hereunder, the matter, upon written request of either Party, shall first be referred to the chief executive officers of the Parties for decision. Such chief executive officers shall promptly meet in a good faith effort to resolve the dispute.

### **17.2 Arbitration.**

**17.2.1 Generally.** Except as provided in Section 17.2.2, if any dispute described in Section 17.1 other than a dispute that arises under the patent laws of a country cannot be resolved by the chief executive officers of the Parties within sixty (60) days after its submission, then such dispute shall be settled by binding arbitration held in Wilmington, Delaware in accordance with the Commercial Arbitration Rules of the American Arbitration Association except that (a) there shall be three U.S.-licensed attorneys acting as arbitrators, (b) the arbitration proceedings shall be kept confidential and shall not be disclosed to the public and (c) payment of the expenses of the arbitration, including legal fees for both Parties and the fee of the arbitrators, shall be assessed by the arbitrators based on the extent to which each party prevails. Each Party shall select one arbitrator. The two arbitrators selected by the Parties shall select the third arbitrator. At least one of the arbitrators shall be a licensed attorney who has represented pharmaceutical companies for at least ten years and is knowledgeable concerning the type of

subject matter at issue in the dispute. The award of the arbitrators shall be in writing and shall be binding on the Parties, and judgment upon the award rendered by the arbitrators may be entered in any federal court having jurisdiction. Any decision or award made by the arbitrators shall be in accordance with the terms and conditions of this Agreement and shall not be inconsistent with the rights and obligations of the Parties as set forth in this Agreement. Nothing in this Agreement bars the right of either Party to obtain preliminary or permanent injunctive relief against threatened conduct that will cause it loss or damage, in accordance with the rules for obtaining injunctive relief in any jurisdiction, including the applicable rules for obtaining restraining orders and preliminary injunctions.

**17.2.2 Baseball Arbitration.** Notwithstanding anything to the contrary in Section 17.2.1, if the Parties or a committee or subcommittee established under this Agreement are unable to agree on any matter that is subject to arbitration under Section 17.2.2 of this Agreement, then either Party may give the other a written notice requesting arbitration to determine such matter (a "**Baseball Arbitration Notice**"), in which case the matter shall be determined by binding arbitration as follows ("**Baseball Arbitration**");

- (a) The Parties to the Baseball Arbitration shall be Advancis and Par;
- (b) The Parties shall jointly select a single arbitrator within 15 days after the giving of the Baseball Arbitration Notice.
- (c) Within 30 days after the appointment of the arbitrator, each Party shall submit a written report to the arbitrator and to the other party, which report shall set forth the party's determination of the matter in dispute (each, a "**Proposal**"). Such report may include such supporting documentation and related calculations as the Party submitting the Proposal deems appropriate.
- (d) Except as otherwise specified in this Section 17.2.2, the Baseball Arbitration shall be conducted in accordance with Section 17.2.1 hereof.
- (e) The arbitrator in any Baseball Arbitration shall have only the authority to select the Proposal proposed by one of the parties to the arbitration, based on which Proposal the arbitrator believes constitutes the better estimate of the Parties' intentions under this Agreement. The arbitrator shall not have the authority to impose additional terms or a compromise of the two Parties' Proposals.
- (f) The parties agree that the decision of the arbitral tribunal rendered in accordance with this Section 17.2.2 will be final and binding. The Parties shall sign all papers and take all actions that are required to obligate the Parties with respect to and effectuate such decision and specific performance may be ordered by any court of competent jurisdiction.

**ARTICLE XVIII  
MISCELLANEOUS**

**18.1 Publicity.** Neither Party shall originate any publicity, news release or other public announcement, written or oral, relating to this Agreement or the existence of a collaboration between the Parties, without the prior written approval of the other Party except as otherwise permitted by this Agreement or required, in the reasonable judgment of the disclosing party's attorneys, by applicable law, including the Securities Act of 1933, as amended, and the rules and regulations thereunder or as promulgated by an applicable securities exchange governing body.

**18.2 Assignment.** During the Term, neither this Agreement, nor any of the Patent Rights licensed hereunder, nor any of the other rights or obligations hereunder may be assigned by either Party without the prior written consent of the other Party, which consent shall not be unreasonably withheld, except that either Party may assign this Agreement and/or any or all of its Patent Rights and/or other rights or obligations hereunder without such consent to an Affiliate or to a party who acquires all or substantially all of the assets of the assigning Party, whether through merger, acquisition, consolidation or otherwise, provided in each instance that such acquiring Party agrees to be subject to and bound by all of the terms and conditions of this Agreement. Any purported assignment in contravention of this Section 18.2 shall be null and void and of no effect.

**18.3 Governing Law.** This Agreement shall be governed by and interpreted in accordance with the internal laws of the State of Delaware, without reference to the conflicts of laws provisions thereof. Subject to Section 17.2: (a) each Party irrevocably submits to the jurisdiction of any state or federal trial court of competent subject matter jurisdiction in the State of Delaware for the purposes of any suit, action or other proceeding arising out of this Agreement or any transaction contemplated by this Agreement (and agrees not to commence any action, suit or proceeding relating to this Agreement or any such transaction, except in those courts), except for any patent infringement suit brought against any third party by a Party hereto; (b) each Party further agrees that service of any process, summons, notice or document in accordance with Section 18.6 shall be effective service of process for any action, suit or proceeding with respect to any matters to which it has submitted to jurisdiction as set forth in the immediately preceding sentence; and (c) each Party irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding arising out of this Agreement or the transactions contemplated by this Agreement in any state or federal trial court of competent jurisdiction in the State of Delaware, and further irrevocably and unconditionally waives and agrees not to plead or claim in any such action, suit or proceeding brought in any such court that such action, suit or proceeding has been brought in an inconvenient forum. The rights and obligations of the Parties under this Agreement shall not be governed by the provisions of the U.N. Convention on Contracts for the International Sale of Goods.

**18.4 Force Majeure.** In the event that either Party fails to perform any of its obligations under this Agreement (other than an obligation to pay money) due to any act of God, fire, casualty, flood, war, strike, lockout, failure of public utilities, injunction, act of a governmental authority (including enactment of any governmental law, order or regulation permanently or temporarily prohibiting or reducing the level of research, development or

production work hereunder or the manufacture, use or sale of the Products), epidemic, destruction of production facilities, riot, insurrection, inability to procure or use materials, labor, equipment, transportation or energy in quantities sufficient to meet experimentation or manufacturing needs, or any other cause beyond the reasonable control of the Party invoking this Section 18.4, provided, in each case, that such Party shall have used Commercially Reasonable Efforts to avoid such failure, then such Party shall promptly give written notice of such occurrence to the other Party, and thereupon the affected Party's performance shall be excused and the time for performance shall be extended for the period of delay or inability to perform due to such occurrence.

**18.5 Waiver.** The waiver by either Party of a breach or a default of any provision of this Agreement by the other Party shall not be construed as a waiver of any succeeding breach of the same or any other provision, nor shall any delay or omission on the part of either Party to exercise or avail itself of any right, power or privilege that it has or may have hereunder operate as a waiver of any right, power or privilege by such Party.

**18.6 Notices.** Any and all notices or other communications made or given pursuant to this Agreement shall be in writing and shall be delivered (i) by express overnight [or two-day international] courier service, (ii) by certified or registered mail, return receipt requested, or (iii) by confirmed facsimile or other electronic transmission (with confirming copy to follow by express overnight courier service):

(a) if to Advancis, at 20425 Seneca Meadows Parkway, Germantown, Maryland 20876, or at such other address or addresses as may be furnished in writing by Advancis to Par, Attention: Kevin S. Sly, Senior Vice President and Chief Business Officer, with copies to: Piper Rudnick LLP, 6225 Smith Avenue, Baltimore, Maryland 21209 (Fax 202-580-3001) Attn: Howard S. Schwartz, Esq.

(b) if to Par, at 300 Tice Boulevard, Woodcliff, New Jersey 07677, Attention: Paul V. Campanelli, Vice President, Business Development, or at such other address or addresses as may be furnished in writing by Par to Advancis, with copies to: Par's General Counsel at the same address and to Frommer Lawrence & Haug, 745 Fifth Avenue, New York, New York 10151 (Fax 212-588-0800) Attn: Arthur Hoag, Esq.

Notices provided in accordance with this Section 18.6 shall be deemed delivered upon receipt of the notice by the Party being sent the notice.

**18.7 No Agency.** Nothing herein shall be deemed to constitute either Party as the agent or representative of the other Party, or both Parties as joint venturers or partners for any purpose. Advancis shall be an independent contractor, not an employee or partner of Par, and the manner in which Advancis performs its obligations under this Agreement shall be within Advancis's sole discretion. Par shall be an independent contractor, not an employee or partner of Advancis, and the manner in which Par performs its obligations under this Agreement shall be within Par's sole discretion (subject to Par's compliance with its obligations under this Agreement). Neither Party shall be responsible for the acts or omissions of the other Party, and

neither Party shall have authority to speak for, represent or bind the other Party in any way without prior written authority from the other Party.

**18.8 Entire Agreement.** This Agreement and the Exhibits and Schedules attached hereto (which Exhibits and Schedules are deemed to be a part of this Agreement for all purposes) contain the full understanding of the Parties with respect to the subject matter hereof and supersede all prior understandings and writings relating thereto. No waiver, alteration or modification of any of the provisions hereof shall be binding unless made in writing and signed on behalf of the Parties by their respective officers thereunto duly authorized.

**18.9 Headings; Interpretation.** The section headings contained in this Agreement are for convenience of reference only, do not form a part of this Agreement and shall not affect in any way the meaning or interpretation of this Agreement. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The words "include," "includes" and "including" shall be deemed to be followed by the phrase "but not limited to." All references herein to Articles, Sections and Exhibits shall be deemed references to Articles and Sections of, and Exhibits to, this Agreement unless the context shall otherwise require. All Exhibits and Schedules attached to this Agreement shall be deemed incorporated herein by reference as if fully set forth herein. Words such as "herein," "hereof," "hereto," "hereby" and "hereunder" refer to this Agreement and to the Exhibits, taken as a whole. Except as otherwise expressly provided herein: (a) any reference in this Agreement to any agreement shall mean such agreement as amended, restated, supplemented or otherwise modified from time to time; and (b) any reference in this Agreement to any law shall include corresponding provisions of any successor law and any regulations and rules promulgated pursuant to such law or such successor law.

**18.10 Severability.** In the event that any provision of this Agreement is held by a court of competent jurisdiction to be unenforceable because it is invalid or in conflict with any law of any relevant jurisdiction, the validity of the remaining provisions shall not be affected, and the rights and obligations of the Parties shall be construed and enforced as if the Agreement did not contain the particular provisions held to be unenforceable.

**18.11 Successors and Assigns.** This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their permitted successors and assigns.

**18.12 Counterparts.** This Agreement may be executed in any number of counterparts (including signature by facsimile), each of which shall be deemed an original but all of which together shall constitute one and the same instrument.

**18.13 Export Controls.** Each Party acknowledges that it is subject to United States laws and regulations controlling the export of technical data, computer software, laboratory prototypes and other commodities (including the Arms Export Control Act, as amended and the United States Department of Commerce Export Administrations Regulations). The transfer of such items may require a license from the cognizant agency of the United States Government and/or written assurances by Par or Advancis that it shall not export data or commodities to certain foreign countries without prior approval of such agency. Neither Party makes any

representation as to whether any such license will be required or, if required, whether it will be issued.

**18.14 Further Assurances.** Each Party hereby agrees, without further consideration, to execute and deliver such documents and take such other actions as the other Party may reasonably request to carry out the provisions hereof and further the Collaboration.

**Execution**

IN WITNESS WHEREOF, the Parties hereto have caused this Development and Commercialization Agreement to be executed as a sealed instrument in their names by their properly and duly authorized officers or representatives as of the date first above written.

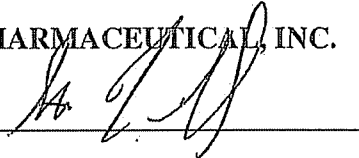
**ADVANCIS PHARMACEUTICAL CORPORATION**

By: 

Print Name: EDWARD M. RUDNIK

Title: CHAIRMAN & CEO

**PAR PHARMACEUTICAL, INC.**

By: 

Print Name: SCOTT TARRIFF

Title: PRESIDENT & CEO



## EXHIBIT A

### EXCLUSION FROM PRODUCTS

Any formulation comprising a Compound with a pharmacokinetic profile that (i) achieves a statistically significant decrease in bacterial counts of at least two (2) logs compared to non-treated controls in the Woodnutt Berry Infection Model, or some other appropriate model proposed by Advancis, against both the 30005S and 16001S *S. pneumoniae* strains and both the 401225 and Chesterfield *H. influenzae* strains each with an amoxicillin minimum inhibitory concentration of 4/2 mcg/mL or higher, or (ii) has a label claim approved by FDA or another comparable regulatory agency in any country for in vitro susceptibility or clinical efficacy against *S. pneumoniae* or *H. influenzae* with an amoxicillin minimum inhibitory concentration of 2mcg/mL or higher.

As used herein, "*Woodnutt Berry Infection Model*" means the models, tests and methods described in the following article: Woodnutt, G. and Berry V., *Two Pharmacodynamic models for assessing the efficacy of amoxicillin-clavulanate against respiratory tract infections caused by strains of Streptococcus pneumoniae*, *Antimicrobial Agents and Chemotherapy*, 1999; Volume 43(1), pages 29-34.

The contents of this Exhibit A are hereby incorporated into the Agreement and are governed by the terms and conditions of the Agreement.

## EXHIBIT B

### FINANCIAL PLANNING SCHEDULE

This Exhibit B covers financial planning, accounting policies and procedures to be followed in determining Development Costs and Operating Profits and related issues regarding sharing and allocation of revenue and expenses pursuant to the Agreement.

For purposes of this Exhibit B only, the consolidated accounting of operations for the collaboration of the Parties under the Agreement shall be referred to as the “*Collaboration*.” The Collaboration is not a legal entity, pass through or otherwise, for financial accounting or income tax reporting purposes, and has been defined for identification purposes only.

This Exhibit B also provides agreed upon definitions of financial, accounting and related terms applicable to the Parties for purposes of the Agreement. All capitalized terms used herein without definition shall have the meanings ascribed thereto in the Agreement, unless otherwise expressly provided herein.

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

**B.1.1 “*Development Costs*”** means all direct and indirect costs and expenses incurred by Advancis pursuant to the budget set forth in the Development Program, which may include (a) costs associated with designing, planning and conducting Phase III Studies for the Products and all subsequent clinical testing and trials, including in vitro and in vivo models, and (b) costs in connection with seeking and obtaining Regulatory Approval, including all FDA filing fees, (c) internal costs of Advancis personnel for salaries and other compensation that are related to the fulfillment of the Development Program paid by Advancis to its FTE’s working on the Development Program, calculated by multiplying the number of FTE’s utilized for such purpose by the FTE Rate, (d) payments made to Third Parties that are authorized by the Development Plan, (e) materials and supplies, and (f) license or acquisition fees and other costs and expenses associated with Advancis’s obtaining from a third party any trademarks, tradenames, logos, trade dress or similar intellectual property rights licensed or acquired by Advancis after the Effective Date for use in connection with the Commercialization of the Product.

**B.1.2 “*FTE*”** means a full time equivalent employee (i.e., one fully-committed or multiple partially-committed employees aggregating to one full-time employee) employed by a Party and assigned to perform specified work, with such commitment of time and effort to constitute one employee performing such work on a full-time basis, which for purposes hereof shall be 1,760 hours per year.

**B.1.3 “*FTE Rate*”** means \$142.05 per hour worked per FTE, which is the equivalent of \$250,000 per year per full-time FTE. The FTE Rate will change each year in accordance with the annual percentage change in the Consumer Price Index (U.S. Bureau of Labor Statistics for all urban consumers, U.S. city average-all items).

**B.1.4 “*Manufacturing Costs*”** means, with respect to any sale of Products, the actual, out-of-pocket expense for obtaining such Products from the manufacturer thereof, including

costs of raw materials, equipment, packaging, labeling, packing, shipping, storage, and other fixed costs, in each case whether such amounts are payable directly to the manufacturer or to a third party or to Advancis. Manufacturing Costs do not include Collaboration Payments, if any, included in the price for Product.

**B.1.5 “Net Sales of Products”** means the actual invoiced gross sales of Products to Third Parties by Par, its Affiliates and their Marketing Distributors, as recorded by Par in accordance with generally accepted accounting principals, less the following: (i) usual and customary allowances or credits to such third parties for spoiled, damaged, rejected, recalled, outdated and returned Products; (ii) freight, transportation, warehousing, storage, postage and insurance charges to the extent separately identified on an invoice; (iii) the amounts of trade, quantity and cash discounts actually allowed, to the extent such trade, quantity and cash discounts are specifically allowed on account of the purchase of such Products; (iv) sales taxes, excise taxes, use taxes, value added taxes and import/export duties actually due or incurred or allowed in connection with the sales of Products to any third party to the extent separately identified on an invoice; (v) usual and customary allowances, adjustments, reimbursements, discounts, chargebacks and rebates granted to third parties, including rebates given to health care organizations or other third parties, whether during the actual period or not; and (vi) usual and customary allowances for doubtful accounts and actual chargeoffs for bad debt. “*Net Sales of Products*” excludes any amounts invoiced or received in connection with any transfers of a Product between Par and its Affiliates prior to final disposition to third party customers but only where Products are to be resold to a third party. “Net Sales of Products” also excludes transfers of Products made or used for tests or development purposes, or distributed as donations or Samples and for which no payment is received by Par or its Affiliates or sublicensees. In the event that Par or its Affiliate or sublicensee, as the case may be, sells, transfers or disposes of any Product for consideration, in whole or in part, other than cash, the gross amount used for calculating Net Sales of Products for such Product shall be deemed to be the standard invoice price then being invoiced in arm’s length transactions with similar customers. In the event that Par sells a Product as part of a bundle or group sale with other products not covered by the Agreement, and provides a discount, allowance or rebate to the purchaser of such products based on the invoiced prices for all products sold, such discount must be allocated pro rata based on average wholesale prices across all such products and may not be applied disproportionately to the Product sold as part of such bundle.

**B.1.6 “Operating Profits”** means, with respect to the sale of any Product, the difference between Net Sales of Products and Manufacturing Costs for such Product.

**B.1.7 “Premarketing Costs”** means all direct and indirect costs and expenses incurred by the Parties in connection with planning and implementing the Premarketing Program but only to the extent authorized by the then-current Commercialization Plan or otherwise agreed by written agreement of both Parties. Premarketing Costs do not include Development Costs and/or Product Sales Force Costs.

**B.1.9 “Product Sales Force Costs”** means, with respect to each Party, all costs associated with the Sales Representatives of such Party who are conducting Details, including costs associated with salaries, bonus and similar compensation payable to such Sales Representatives, employee benefits, out-of-pocket expenses payable by the Party in connection

with such Details, and the like. Product Sales Force Costs shall not constitute Premarketing Costs or Promotion Costs.

**B.1.10 “Promotion Costs”** means, with respect to each Party, direct and indirect costs and expenses (excluding Product Sales Force Costs) incurred by a Party in connection with the Promotion of Products in the Territory pursuant to and as authorized by the Commercialization Plans. Specific categories of expenses constituting Promotion Costs shall be determined from time to time by the Finance Subcommittee upon consultation with the Sales and Marketing Subcommittee.

## **B.2 PRINCIPLES OF REPORTING.**

The presentation of results of operations of the Parties in the Territory will be based on each Party’s respective financial information presented separately and on a consolidated basis in a reporting format determined by the Finance Subcommittee.

It is the intention of the Parties that the interpretation of these definitions will be consistent with generally accepted accounting principles (“GAAP”) in the U.S.

If necessary, a Party will make the appropriate adjustments to the financial information it supplies under the Agreement to conform to the format of reporting results of operations determined by the Finance Subcommittee. Without limiting the foregoing, prior to the time that Gross Sales are obtained, the Parties may omit any line items related to sales and the support of sales, and the costs thereof, from their respective financial reporting and report only those items relevant to the payment of Development Costs.

## **B.3 FREQUENCY OF REPORTING.**

Reporting by each Party for Collaboration revenues and expenses will be performed as determined by the Finance Subcommittee.

Reports of actual results compared to budget will be made to the Finance Subcommittee on a quarterly basis. After approval by the Finance Subcommittee as to amounts, the Finance Subcommittee will forward the report to the Executive Committee for its approval.

The Finance Subcommittee will be responsible for the preparation of consolidated reporting of the Collaboration (including Development Costs and any Operating Profit). Par will provide the Finance Subcommittee within thirty (30) days of quarter end a statement showing the consolidated results and calculations of the Operating Profit sharing (or calculation of expenses to be shared) in a format determined by the Finance Subcommittee.

Par shall record sales in the U.S.

The Finance Subcommittee will meet as appropriate but at least quarterly to review and approve the following: Development Costs (review only); actual results; forecasts; budgets; inventory levels; Sales Returns and Allowances; and other financial matters, including each Party’s methodologies for charging costs to the Collaboration, for determination of actuals, forecasts, budgets and long range plans and the results of applying such methodologies.

#### **B.4 COMMERCIALIZATION PLAN BUDGETS.**

Budgets will be prepared annually with respect to each Draft Plan and Commercialization Plan. Responsibility for such budgets will rest with the Sales and Marketing Subcommittee, which will develop such budgets, with the assistance of the Finance Subcommittee, subject to final approval by the Executive Committee.

Commercialization Plan budgets will be supplemented with detailed business plans for Product introductions, sales and Promotion efforts as determined by the Finance Subcommittee. Budgets, once approved by the Executive Committee, can only be changed with the approval of the Executive Committee.

The Finance Subcommittee, with the assistance of the Sales and Marketing Subcommittee, will be responsible for identifying, analyzing and reporting all significant line item budget variances and all overall, total budget variances to the Executive Committee. Only the Executive Committee may approve materially unfavorable line item budget variations, as defined by the Finance Subcommittee, and all overall, total budget variations, chargeable to the Collaboration during the course of the year.

Each Party shall be responsible for its own Product Sales Force Costs.

#### **B.5 AUDITS AND REPORTS.**

**B.5.1 Audit.** Par shall keep full, true and accurate books of account containing all particulars as shall be pertinent for the purpose of showing any Collaboration Payments and any other amounts due to Advancis from Par under the Agreement. Such books of account shall be kept at Par's principal place of business. Such books and the supporting data shall be open, at all reasonable times and upon reasonable notice during the term of the Agreement, but no more than four times per calendar year, and for three (3) years after the termination of the Agreement or five (5) years following the end of the calendar year to which they pertain, whichever is shorter, to the inspection of Advancis and its authorized agents (including a certified public accounting firm selected by Advancis), for the purpose of verifying Collaboration Payment reports provided below and compliance in other respects with the Agreement. In the event that any such inspection reveals a deficiency in excess of five percent (5%) of the reported Collaboration Payments for the period covered by the inspection, Par shall promptly pay Advancis (i) the deficiency, plus interest (at the rate payable for overdue payment items pursuant to Section B.5.3) and (ii) the full costs of such inspection. Otherwise, Advancis shall pay the full cost of such inspection.

**B.5.2 Quarterly Reports of Collaboration Payments.** Within thirty (30) days after the end of the calendar quarters ending March 31, June 30 and September 30 of each year and within forty-five (45) days after the end of the calendar quarter ending December 31 of each year, Par shall deliver to Advancis, at its principal place of business specified in the Agreement or at such other address as Advancis shall, from time to time, specify to Par in writing, true and accurate reports, certified by an authorized executive officer of Par, giving such particulars of the business conducted by Par during the preceding three-month period under the Agreement as shall

be pertinent to a Collaboration Payment accounting hereunder, regardless of whether any Collaboration Payments are then due and owing to Advancis by Par.

**B.5.3 Overdue Payments.** Except to the extent provided otherwise in the Agreement, the payment of Development Costs and Collaboration Payments shall, if overdue, bear interest until payment at a per annum rate equal to one and a half percent (1-1/2%) above the prime rate published in The Wall Street Journal on the due date, not to exceed the maximum permitted by law, provided, however that the payment of such interest shall not preclude Advancis from exercising any other rights or remedies it may have as a consequence of the lateness of any Collaboration Payment or other payment due hereunder.

**B.5.4 Additional Information.** Par shall furnish Advancis, and Advancis shall furnish Par, such additional information as the other Party may reasonably request from time to time, to the extent that such information is reasonably available, to ascertain the amount of Collaboration Payments and any other amounts due Advancis under the Agreement.

## **B.6 SHARING PREMARKETING COSTS AND PROMOTION COSTS.**

The Parties shall share equally in the Premarketing Costs and Promotion Costs under the Commercialization Plans and the Agreement. Balancing payments between the Parties for purposes of the sharing of Premarketing Costs and Promotion Costs under the Agreement will be approved by the Finance Subcommittee. Within thirty (30) days after the end of each calendar quarter, there shall be reconciliation of the Premarketing Costs and Promotion Costs which are to be shared and which are incurred during that quarter by the Parties, with a payment by one Party to the other to the extent necessary so that each Party bears one-half of Premarketing Costs and Promotion Costs. In the event any payment is made after thirty (30) days after the end of a calendar quarter, the paying Party shall increase the amount otherwise due and payable by adding interest thereon, computed at the rate specified in Section B.5.3.

## **B.7 RESPONSIBILITY FOR REPORTING.**

The responsibility for the consolidated reporting of the Collaboration to the Finance Subcommittee shall be with Par in close cooperation with Advancis. Such consolidated reports shall, after adjustments, if any, approved by the Finance Subcommittee and the Executive Committee, be the basis for Collaboration accounting and determining of payments to the Parties. Par shall provide the Finance Subcommittee with a Collaboration consolidated reporting and its proposed calculation of payments to the Parties no later than 45 days after the end of each Quarter. Advancis shall provide Par with financial statements for their Commercialization activities in the Territory, prepared in accordance with the terms contained in this Exhibit B, within thirty (30) days after the end of each Quarter in order for Par to prepare the consolidated reports.

## **B.8 ACCOUNTING FOR DEVELOPMENT COSTS, MANUFACTURING COSTS AND PROMOTION COSTS.**

The Finance Subcommittee shall establish policies and procedures pursuant to which the Premarketing Costs, Development Costs, Manufacturing Costs and Promotion Costs incurred by the Parties shall be determined. Each Party shall report its costs in accordance with the

accounting policies and procedures established by the Finance Subcommittee and shall not seek reimbursement from the Collaboration for any costs in excess of such amounts.

**B.9 PAYMENTS TO ADVANCIS OUT OF OPERATING PROFITS.**

**B.9.1 Payments.** Par shall pay to Advancis the Collaboration Payments derived from the sale of Products in the Territory, in an amount equal to fifty percent (50%) of Operating Profits allocable to such sales.

**B.9.2 Payment Terms.** Operating Profits shall be determined on a calendar quarter by calendar quarter basis. Par shall pay Collaboration Payments, if any, to Advancis for each calendar quarter within thirty (30) days after the end of such calendar quarter in which Net Sales of Products by Par occur, such payment to be made by wire transfer of immediately available funds, in United States dollars, to an account designated in advance by Advancis. Each payment of Collaboration Payments by Par shall be accompanied by a copy of a calculation of the amount due and payable, including a statement as to all material information relevant to such calculation, including a statement as to Net Sales of Products and Manufacturing Costs, including all components thereof, and shall be final, non-refundable and not subject to adjustment.

**B.9.3 Taxes.** Par shall be responsible for paying all taxes (including any related interest or penalties), however designated, imposed as a result of the payment of any Royalties, including any sales and value added taxes and any tax which Par is required to withhold or deduct from payments to Advancis, and the Collaboration Payments paid to Advancis shall not be reduced as a result of the payment by Par of any such taxes.

**B.9.4 Repayment of Development Costs to Advancis.** Notwithstanding anything to the contrary set forth above in this Section B.9 or elsewhere in the Agreement, prior to the retention by Par of any of its fifty percent (50%) share of the Operating Profits generated from the sale of Products, Advancis shall first be paid out of such Par share of Operating Profits an amount equal to any Development Funding Gap then outstanding, or, if less, the total amount of such Par share of Operating Profits. Such payment shall be made at the same time as corresponding Collaboration Payments are made to Advancis.

**B.10 PAYMENT OF DEVELOPMENT COSTS.**

Development Costs shall be paid by Par as follows:

**B.10.1** Par shall pay the Development Costs to Advancis in periodic payments as follows:

<b>Payable on or before</b>	<b>Installment Amount</b>
July 1, 2004	\$4,500,000
October 1, 2004	\$4,500,000
January 1, 2005	\$4,750,000
April 1, 2005	\$4,750,000
July 1, 2005	\$4,750,000
October 1, 2005	\$4,750,000
Total:	\$28,000,000

**B.11 START OF OPERATIONS AND EFFECTIVE ACCOUNTING DATE TERMINATION.**

Operation of the Collaboration will be deemed to have commenced as of the Effective Date.

For reporting and accounting purposes with respect to the Collaboration, the effective termination date of the Agreement with regard to the last Detailing year in the Territory will be the nearest month end to which such termination takes place.



## EXHIBIT C

### COMMERCIALIZATION PARAMETERS AND DETAILING SCHEDULE

This Exhibit C covers Detailing and Promotional activities to be undertaken by the Parties in connection with the Commercialization of the Products pursuant to the Agreement.

This Exhibit C provides agreed upon definitions of terms applicable to the Parties' Detailing, Promotional, and related Commercialization efforts under the Agreement. All capitalized terms used herein without definition shall have the meanings ascribed thereto in the Agreement, unless otherwise expressly provided herein.

#### DEFINITIONS

**C.1.1 "Detail"** means a face-to-face meeting of a Sales Representative with a medical professional having prescribing authority, during which meeting scientific and/or medical information about the Products is discussed for the purpose of encouraging sale of the Products. A Detail does not include a reminder or Sample drop. Details shall be measured by each Party's internal recording of such activity; provided that, such measurement shall be on the same basis as the recording Party's measurement for its representatives that are comparable to Sales Representatives with respect to detailing of such recording Party's other products, consistently applied throughout the Term. When used as a verb, the term "**Detailing**" means to engage in the activity of a Detail.

**C.1.2 "Detailing Priorities"** means, with respect to each Party, the priority position in which the Parties' Sales Representatives are required to Detail the respective Products to a particular Targeted Prescriber, as compared with other products being detailed by such Party. The Products shall be Detailed only in the first Detail position, with at least [50%] of the Detail time devoted to the Products.

**C.1.3 "Detailing Requirements"** means the number of Details, Detailing Priorities, and other aspects of Detailing directed to Targeted Prescribers required of each Party in a given measurement period during the Term, as set forth in the Commercialization Plan.

**C.1.4 "Product Sales Force"** means, with respect to each Party, a sales and marketing force consisting of an appropriate number of trained and experienced Sales Representatives capable of fulfilling all requirements of such Party under the then-current Commercialization Plan, including compliance with all Detailing Requirements during the respective measurement periods thereof.

**C.1.5 "Promote"** means those activities other than Detailing that are undertaken by a Party in order to encourage sales of Products, including journal advertising, direct mail programs, direct-to-consumer advertising, convention exhibits and other forms of advertising and promotion.

**C.1.6 “Sales Representative”** means an individual who engages in Detailing and similar sales efforts in the United States with respect to the Products on a full-time basis.

**C.1.7 “Targeted Prescribers”** means the set of physicians or other authorized prescribers that the Parties expect to include in the Commercialization Plans as the principal focus of their Commercialization efforts.

The Parties hereby agree to the following commercial objectives, which shall be reflected in the Commercialization Plans:

**C.2.1** Secure 30% share of prescriptions in the amoxicillin market segment

**C.2.2** Deliver not less than 1 million Details to Targeted Prescribers of amoxicillin, in the first twelve-month period following approval.

**C.2.3** Establish category leadership in journal advertising and medical education programs as measured by generally-accepted industry audits that track Promotional spending

**C.2.4** Deliver 1.5 million Sample units to Targeted Prescribers

**C.2.5** Achieve 90% brand awareness at launch among Targeted Prescribers

**C.2.6** Gain preferred formulary status at 90% of major managed care organizations

**C.2.7** Achieve 95% stocking levels at high volume retail pharmacies

**C.2.8** Establish 100 Product citations in the medical literature prior to launch

The Parties agree that the following strategies shall be incorporated into the Commercialization Plans:

**C.3.1 Data Dissemination Strategy.** Leverage relationships developed with experts in the field of anti-infectives to generate scientific hypothesis, data, and publications that support the strategic goals of amoxicillin PULSYS.

**C.3.2 Advocacy Strategy.** Leveraging scientific evidence supporting amoxicillin PULSYS, build external advocates for the product within the scientific and medical community for the purpose of influencing prescribing behavior, medical guideline development, and general perception of amoxicillin PULSYS in the market place.

**C.3.3 Managed Care Strategy.** Secure broad formulary coverage by building a sound clinical and economic case supporting access and coverage while maximizing profitability.

**C.3.4 Targeted Prescriber Detailing Strategy.** Focused detailing effort directed at high volume prescribers responsible for generating majority of prescriptions generated in the aminopenicillin market.

**C.3.5 Medical Education Strategy.** Utilize scientific and clinical data supporting amoxicillin PULSYS to create medical education programs and opportunities for medical, scientific, and health care professionals.

**C.3.6 Pharmacy Stocking Strategy.** Build and leverage relationships with the trade and specifically major chains and distributors to ensure forced distribution of amoxicillin PULSYS product presentations to retail outlets at launch. To the extent possible, create stocking incentive programs that secure desired reach while maintaining profitability goals. Augment

national accounts efforts with mail and telemarketing initiatives designed to drive demand among retail outlets.

**C.3.7 Accelerated Adoption Strategy.** Identify and target early adopters and key opinion leaders for involvement in “early access” or “real world” experience studies to accelerate their adoption of amoxicillin PULSYS.

**C.3.8 Phase IIB/IV Clinical Evidence Strategy.** Engage leading investigators in the anti-infective field in the design and execution of additional phase IIB/IV studies to support the commercial objectives of amoxicillin PULSYS.

The Parties agree that matters relating to pre-Commercialization activities and expenses on which the Parties do not agree shall be submitted to the Sales and Marketing Subcommittee for review in accordance with Section 3.3.

## EXHIBIT D

### DEVELOPMENT AND COMMERCIALIZATION ACTIVITIES FOR COUNTRIES OUTSIDE OF THE UNITED STATES

Subject to the provisions of this Agreement, Advancis has appointed Par as its sole distributor of the Products in the Territory. This Exhibit D covers development and Commercialization activities and related issues with respect to the parties' goals and efforts to Commercialize the Products outside of the United States.

This Exhibit D also provides agreed upon definitions of financial, accounting and related terms applicable to the Parties for purposes of the Agreement. All capitalized terms used herein without definition shall have the meanings ascribed thereto in the Agreement, unless otherwise expressly provided herein. References in this Exhibit D to a "*Party*" or "*Parties*" shall be construed to mean Advancis or Par.

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

**D.1.1** "*Ex-U.S. Country*" means a country in the Ex-U.S. Territory.

**D.1.2** "*Ex-U.S. Territory*" means the countries in the Territory that are not the United States and its possessions as of the Effective Date, as the same may be changed in accordance with the provisions of this Exhibit D.

**D.1.3** "*Ex-U.S. Regulatory Authority*" means any court, tribunal, arbitrator, agency, commission, official or other instrumentality of any federal, state, county, city or other political subdivision, that performs a function for such political subdivision similar to the function performed by the FDA for the United States with regard to the approval, licensing, registration or authorization to test, manufacture, promote, market, distribute, use, store, import, transport or sell a product in the applicable territory or political subdivisions, or with respect to the approval of pricing or reimbursement for such product.

**D.1.4** "*MAA*" or "*Marketing Approval Application*" means a marketing authorization application (including or comparable to an NDA), including all supporting documentation and data submitted for such application to be accepted for review or approval, filed with the requisite Ex-U.S. Regulatory Authority of any Ex-U.S. country, and requesting approval for Commercialization of Products for a particular indication in such country.

**D.1.5** "*MAA Approval*" means, with respect to any Ex-U.S. country, approval by the applicable Ex-U.S. Regulatory Authority in such country of an MAA filed in such country, permitting Products to be marketed in that country for the indication(s) for which approval is sought, including, if applicable, approval of pricing or reimbursement.

## **D.2 EX-U.S. PLANNING SUBCOMMITTEE.**

**D.2.1** Within 180 days after the Effective Date, the Parties shall establish a Subcommittee (the "*Ex-U.S. Planning Subcommittee*") with responsibility for identifying priorities relating to the development, product selection, regulatory approval and Commercialization of Products in the Ex-U.S. Countries, on a country by country basis and performing such other duties as may be assigned under this Agreement or as may be delegated to the Ex-U.S. Planning Subcommittee by the Executive Committee; provided that nothing in this Section F.2.1 shall limit the rights or obligations of the Parties in this Agreement.

**D.2.2** Each Party shall appoint two designees to the Ex-U.S. Planning Subcommittee, each of whom shall have expertise and experience in the areas of development, regulatory approval, marketing, Promotion, advertising and sales. Either Party may replace any or all of its designees on the Ex-U.S. Planning Subcommittee at any time upon written notice to the other Party, and any member of the Ex-U.S. Planning Subcommittee may designate a suitable proxy to perform the functions of that member at any time. In addition, the Ex-U.S. Planning Subcommittee shall seek to act with the unanimous consent of the members of the Ex-U.S. Planning Subcommittee. In the event that the Ex-U.S. Planning Subcommittee members do not reach consensus with respect to a matter that is within the purview of the Ex-U.S. Planning Subcommittee, the Ex-U.S. Planning Subcommittee designees of each Party shall collectively have one vote for purposes of decision-making hereunder with respect to such matters, with decisions made by unanimous vote. If the votes of the Ex-U.S. Planning Subcommittee are split on any matter, such matter shall be referred (by way of the Alliance Managers) to the Executive Committee for decision. Any matter that is not decided by the unanimous consent of all members of the Executive Committee shall be subject to resolution by the chief executive officers of the Parties pursuant to Section 17.1 and, thereafter, by arbitration in accordance with Section 17.2.2.

## **D.3 DEVELOPMENT AND COMMERCIALIZATION PLANS.**

**D.3.1** The Ex-U.S. Planning Subcommittee shall work together in good faith after the second anniversary of the Effective Date to commence the negotiation and formulation of a detailed plan and budget for the development and Commercialization of the Products in each country in the Ex-U.S. Territory (with respect to each such country, the "*D&C Plan*"). Any country for which the Ex-U.S. Planning Subcommittee does not prepare a preliminary D&C Plan in accordance with the provisions of this Exhibit D shall, as of the third anniversary of the Effective Date, no longer be part of the Ex-U.S. Territory; provided that such period shall be tolled in the event of a bona fide dispute between the Parties with respect to a proposed D&C Plan for any Ex-U.S. Country that has been submitted to the Executive Committee (or thereafter to arbitration pursuant to Section 17.2.2) for resolution.

**D.3.2** The Ex-U.S. Planning Subcommittee shall submit a preliminary D&C Plan to the Executive Committee for approval no later than the third anniversary of the Effective Date. Upon receipt of such preliminary D&C Plan, the Executive Committee shall negotiate in good faith and take such other steps as may be necessary to adopt a final approved D&C Plan not later than 180 days thereafter. Changes to the approved D&C Plan may be made at any time and from time to time upon prior written agreement of both Parties or prior approval of the Executive Committee. Any country for which the Executive Committee does not approve a D&C Plan in

accordance with the provisions of this Exhibit D shall, as of the date that is 180 days after the third anniversary of the Effective Date, no longer be part of the Ex-U.S. Territory; provided that such period shall be tolled in the event of a bona fide dispute between the Parties with respect to a proposed D&C Plan for any Ex-U.S. Country and such dispute is being resolved by the chief executive officers of the Parties pursuant to Section 17.1 and, thereafter, by arbitration in accordance with Section 17.2.2.

**D.3.3** Each D&C Plan shall provide that: (a) Par shall be solely responsible for all costs of development, including obtaining MAA Regulatory Approval in the subject country; (b) Par shall have the sole right to book sales of the Products in the subject country; (c) Advancis will own all MAA Approvals in the subject country; (d) Advancis will be solely responsible for the manufacturing of Products relating to the development and Commercialization of the Products in the subject country; (e) the Parties will have co-marketing rights in the subject country; and (f) the Parties shall be equally responsible for costs of Commercialization of the Products in the subject country. By mutual agreement of the Parties, any of the foregoing obligations may be assumed, in whole or in part, by one or more third parties.

**D.3.5** Advancis shall own in their entirety (a) all clinical data and reports related to clinical trials for the Products, and (b) all MAAs and MAA Approvals for Products.

**D.4 EX-U.S. DEVELOPMENT AND SALES AND MARKETING.**

**D.4.1** Promptly after the approval by the Executive Committee of each D&C Plan, each of the Development and Manufacturing Subcommittee and the Sales and Marketing Subcommittee shall assume its respective role with regard to the such functions in the subject Ex-U.S. Country.

**D.4.2** The provisions of this Agreement shall apply to all Ex-U.S. Country development, manufacturing, sales and marketing efforts, as adjusted by the Parties through one or more appropriate written amendments to this Agreement, which may be on a country-by-country basis.

**Execution**

IN WITNESS WHEREOF, the Parties hereto have caused this Development and Commercialization Agreement to be executed as a sealed instrument in their names by their properly and duly authorized officers or representatives as of the date first above written.

**ADVANCIS PHARMACEUTICAL CORPORATION**

By: 

Print Name: Edward M. Rudnik

Title: Chairman & CEO

**PAR PHARMACEUTICAL, INC.**

By: 

Print Name: Scott Tarrieff

Title: President & CEO

## **EXHIBIT B**



**FIRST AMENDMENT TO  
DEVELOPMENT AND COMMERCIALIZATION AGREEMENT**

This Amendment to Development and Commercialization Agreement (this "*Amendment*") is made and entered into this Fourteenth day of December, 2004 (the "*Effective Date*"), by and between Advancis Pharmaceutical Corporation, a Delaware corporation ("*Advancis*"), and Par Pharmaceutical, Inc., a Delaware corporation ("*Par*").

WHEREAS, Advancis and Par are parties to that certain Development and Commercialization Agreement dated May 28, 2004 (the "*Development and Commercialization Agreement*"); and

WHEREAS, Advancis and Par wish to modify the Development and Commercialization Agreement so that the development and commercialization of an amoxicillin-only product for the pediatric population targeting acute otitis media will be replaced by the development and commercialization of an amoxicillin clavulanic acid product for such indication, in accordance with the terms of this Amendment.

NOW, THEREFORE, in consideration of the mutual covenants and promises contained in this Amendment and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Advancis and Par agree as follows:

1. Definitions; Format. All capitalized terms not otherwise defined in this Amendment shall have the definitions ascribed to such terms in the Development and Commercialization Agreement. Where a textual passage is amended in part only, new language will be shown double underlined, deleted language will be shown in ~~strikeout~~, and language that is unmodified will be shown as an ellipsis ("..."). Double underlining, deleted language and ellipses are for convenience only and are not part of the Development and Commercialization Agreement, as amended.

2. Development Plan. Pursuant to Section 4.1 of the Development and Commercialization Agreement, the Development Plan had been agreed to by the Parties by letter dated June 2, 2004. The Parties agree to work together in good faith to mutually agree in writing upon an amended and restated Development Plan within one week of the Effective Date of this Amendment which will reflect the modifications to the Development Program set forth in this Amendment (the "*Amended and Restated Development Plan*"). The Amended and Restated Development Plan will be substantially similar to the most recent development plan materials circulated by Advancis to Par as of the date of this Amendment.

3. Modification of Definition of Compound. Section 1.20, the definition of "Compound" is amended to read as follows:

"Compound" means, individually and collectively, as applicable, the Amox-Only Compound and the Amox-Clav Compound, the compound amoxicillin, including all racemates, chelates, complexes, enantiomers, diastereoisomers, salts, bases, esters, hydrates, solvates, polymorphs, crystal forms, crystal habits,

~~prodrugs, isotopic or radiolabeled equivalents, metabolites, or the like, thereof and all mixtures of any of the foregoing.~~

4. Addition of New Definition of Amox-Only Compound. A new Section 1.20.1, the definition of “Amox-Only Compound” is inserted to read as follows:

“Amox-Only Compound” means the compound amoxicillin, including all racemates, chelates, complexes, enantiomers, diastereoisomers, salts, bases, esters, hydrates, solvates, polymorphs, crystal forms, crystal habits, prodrugs, isotopic or radiolabeled equivalents, metabolites, or the like, thereof and all mixtures of any of the foregoing.

5. Addition of New Definition of Amox-Clav Compound. A new Section 1.20.2, the definition of “Amox-Clav Compound” is inserted to read as follows:

“Amox-Clav Compound” means the compounds amoxicillin and clavulanic acid, including all racemates, chelates, complexes, enantiomers, diastereoisomers, salts, bases, esters, hydrates, solvates, polymorphs, crystal forms, crystal habits, prodrugs, isotopic or radiolabeled equivalents, metabolites, or the like, thereof and all mixtures of any of the foregoing.

6. Modification of Definition of Adult Product. Section 1.1, the definition of “Adult Product” is amended to read as follows:

“Adult Product” means a pharmaceutical presentation of the Amox-Only Compound (a) that utilizes or incorporates PULSYS™, and (b) that contains no active pharmaceutical ingredient (including any active pharmaceutical ingredient that acts as an  $\beta$ -lactamase inhibitor) other than the Amox-Only Compound, and (c) that is used or is being developed for the Adult Product Indication, and (e) that is used or is being developed for the Adult Product Indication, other than formulations of Exhibit A.

7. Modification of Definition of Pediatric Product. Section 1.59, the definition of “Pediatric Product” is amended to read as follows:

“Pediatric Product” means, as the case may be, (a) a pharmaceutical presentation of the Amox-Only Compound (a)(i) that utilizes or incorporates PULSYS™, (b)(ii) that contains no active pharmaceutical ingredient (including any active pharmaceutical ingredient that acts as a  $\beta$ -lactamase inhibitor) other than the Amox-Only Compound, and (e)(iii) that is used or is being developed for the Pediatric Product Indications, Streptococcal Pharyngitis; and/or (b) the pharmaceutical presentation of the Amox-Clav Compound (i) that utilizes or

incorporates PULSYS™, that contains no active pharmaceutical ingredient other than the Amox-Clav Compound, and (iii) that is used or is being developed for the Pediatric Product Indication Acute Otitis Media other than formulations of Exhibit A.

8. Modification of Definition of Adult Product Indication. Section 1.2, the definition of “Adult Product Indication” is amended to read as follows:

**“Adult Product Indication”** means Streptococcal Pharyngitis in adolescents/adults in accordance with the protocols set forth in the Amended and Restated Development Plan, (proposed Phase III Studies protocol 111.301), and any other indication agreed to by the Parties.

9. Modification of Definition of Pediatric Product Indications. Section 1.60, the definition of “Pediatric Product Indications” is amended to read as follows:

**“Pediatric Product Indications”** means (i) Streptococcal Pharyngitis ~~(proposed Phase III Studies protocol 231.301);~~ (ii) acute otitis media ~~(proposed Phase III Studies protocol 231.302),~~ both in accordance with the protocols set forth in the Amended and Restated Development Plan,; and (c) any other indications agreed to by the Parties.

10. Deletion of Exhibit A. Exhibit A is deleted from the Development and Commercialization Agreement. In addition, the last sentence of Section 14.2 (No Conflicts), which refers to Exhibit A, is deleted.

11. Modification of Section 2.3 Non-Competition. Section 2.3, “Non-Competition” is amended to read as follows:

**Non-Competition.** During the Term, and except as through the Collaboration pursuant to this Agreement neither ~~p~~Party for the Territory shall develop, market, sell or distribute any pharmaceutical product that requires approval from the Office of New Drugs, wherein (a) the sole active pharmaceutical ingredient in such product is the Amox-Only Compound; or (b) with respect to indications for acute otitis media in the pediatric population, the only active pharmaceutical ingredients in such product are the Amox-Clav Compound. ~~Notwithstanding the foregoing, it is expressly agreed that this Section 2.3 does not apply to any formulations of Exhibit A.~~

12. Section 4.2.2.2. The Parties hereby understand and agree that Section 4.2.2.2 of the Development and Commercialization Agreement shall apply with the following clarifications: (a) the applicable total Development Cost against which proposed percentage increases shall be measured for purposes of determining whether Par may have a termination

right shall be and remain, until the parties otherwise agree, Thirty Nine Million Five Hundred Thousand Dollars (\$39,500,000) which is the total cost of development set forth in the Development Plan agreed to by the parties June 2, 2004, and (b) Par's rights under Section 4.2.2.2 of the Development and Commercialization Agreement shall apply at such time that a proposed increase in the total Development Cost results in the aggregate increases in Development Cost reaching twenty-five percent (25%) of the total Development Cost of Thirty Nine Million Five Hundred Thousand Dollars (\$39,500,000) referenced in (a).

13. No Other Changes: Execution. Except as explicitly set forth in this Amendment, no amendment or modification to the Development and Commercialization Agreement is hereby made. This Amendment may be executed in counterparts and delivered by facsimile.

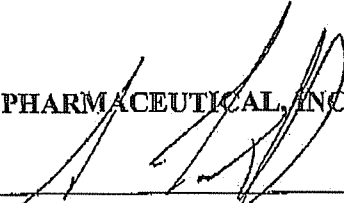
IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to be executed as a sealed instrument in their names by their properly and duly authorized officers or representatives as of the date first above written.

**ADVANCIS PHARMACEUTICAL CORPORATION**

By: 

Print Name: EDWARD M. RUDNIC

Title: CHAIRMAN & CEO

**PAR PHARMACEUTICAL, INC.**  
By: 

Print Name: Scott Tarriff

Title: President + CEO

## **EXHIBIT C**



Par Pharmaceutical Companies, Inc.  
300 Tice Boulevard  
Woodcliff Lake, NJ 07677  
dlr 201 802 4001  
tel 201 802 4000  
fax 201 802 4622  
starriff@parpharm.com  
www.parpharm.com  
**Scott Tarriff**  
President and CEO

Edward Rudnic  
Chairman and CEO  
Advancis Pharmaceutical Corporation  
20425 Seneca Meadows Parkway  
Germantown, MD 20876

RE: Amoxicillin Agreement

Dear Ed:

As we have discussed, the recent failure of the pediatric study combined with the adult study results will increase the development costs and push back the expected product approval date significantly. As a result, I wanted to formally notify you of Par's termination in accordance with the agreement. Such termination notice is intended to cancel the final payment to Advancis due on October 5, 2005, but shall have no impact on Par's obligation to pay Advancis the July 5, 2005 payment.

Please confirm your understanding of the termination of the partnership agreement, including the final payment of October 5, 2005, by signing this letter in the space provided below and returning one copy to my attention. Upon receipt of your signed acceptance, Par will remit the July 5, 2005 payment to Advancis via wire transfer.

Sincerely,

  
Scott Tarriff

Agreed and Accepted

Signature:



Print Name:

EDWARD RUDNIC

Date:

8/3/05

## **EXHIBIT D**

**Amoxicillin Pulsys - Adult & Pediatric\***  
**Life to Date P&L as of 7/31/2010**

	(in 000's) through 12/31/2009	1/1 - 7/31/2010	Life to Date
Gross Sales	\$ 16,635	\$ 7,787	\$ 24,422
Chargebacks	(109)	(78)	(187)
Medicaid Rebates	(178)	(414)	(592)
Returns	(998)	(435)	(1,433)
Cash Discounts	(333)	(159)	(492)
Wholesaler Rebates	(663)	(447)	(1,110)
Coupon POS Discounts	(5,221)	(1,899)	(7,120)
Pricing Discounts	(836)	-	(836)
<b>Net Revenue</b>	<b>8,297</b>	<b>4,356</b>	<b>12,653</b>
COGS - Cost of Goods Sold	794	347	1,141
COGS - Mfg Equipment Depreciation	254	350	604
COGS - Scrap	-	1,700	1,700
<b>Cost of Goods Sold</b>	<b>1,048</b>	<b>2,397</b>	<b>3,445</b>
<b>Gross Margin</b>	<b>\$ 7,249</b>	<b>\$ 1,960</b>	<b>\$ 9,209</b>
Selling & Marketing - 4Q08	2,041	-	2,041
Selling & Marketing - 2009	69,885	-	69,885
Selling & Marketing - 2010	-	9,748	9,748
<b>Selling &amp; Marketing</b>	<b>71,926</b>	<b>9,748</b>	<b>81,674</b>
R&D - life to date 12/31/08	77,776	-	77,776
R&D - 2009	942	-	942
R&D - 2010	-	324	324
<b>Research &amp; Development</b>	<b>78,718</b>	<b>324</b>	<b>79,042</b>
<b>Net Loss</b>	<b>\$ (143,395)</b>	<b>\$ (8,113)</b>	<b>\$ (151,508)</b>

\* The Debtor has not developed nor commercialized the Pediatric Amoxicillin Pulsys product.



# **EXHIBIT E**

## **Proposed Order**

**UNITED STATES BANKRUPTCY COURT  
DISTRICT OF DELAWARE**

In re:	) Chapter 11
	)
MIDDLEBROOK PHARMACEUTICALS, INC., <sup>1</sup>	) Case No. 10-11485 (MFW)
	)
Debtor.	) Docket Ref. No. _____

**ORDER PURSUANT TO 11 U.S.C. § 502 AND FED. R. BANKR. P. 3007  
DISALLOWING AND EXPUNGING PROOF OF CLAIM NO. 59**

Upon the Claim Objection<sup>2</sup> of MiddleBrook Pharmaceuticals, Inc., the above-captioned debtor and debtor in possession (the “**Debtor**”), pursuant to Rule 3007 of the Federal Rules of Bankruptcy Procedure (the “**Bankruptcy Rules**”) and Section 502 of Title 11 of the United States Code (the “**Bankruptcy Code**”), to Proof of Claim No. 59 (the “**POC**”) filed by Par Pharmaceutical, Inc. (“**Par**”) on or about August 18, 2010, in the amount of \$11,625,000 (the “**Claim**”), all as more fully described in the Claim Objection; and the Court having jurisdiction to consider the Claim Objection and the relief requested therein pursuant to 28 U.S.C. §§ 157 and 1334; and consideration of the Claim Objection and the requested relief being a core proceeding pursuant to 23 U.S.C. § 157(b); and venue being proper before this Court pursuant to §§ 1408 and 1409; and due and proper notice of the Claim Objection having been provided; and the relief requested being in the best interests of the Debtor, its creditors and estate; and the Court having reviewed the Claim Objection; and the Court having determined that the legal and factual bases set forth in the Claim Objection establishes just cause for relief granted therein; and after due deliberation and sufficient cause appearing therefore,

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<sup>1</sup> The last four digits of the Debtor’s taxpayer identification number are 8264. The Debtor’s mailing address is 7 Village Circle, Suite 100, Westlake, Texas 76262.

<sup>2</sup> Any capitalized terms not defined herein shall have the meaning ascribed to them in the Claim Objection.

IT IS HEREBY ORDERED THAT:

- 1) the Claim is hereby disallowed and the POC is expunged in its entirety, and
- 2) the Court shall retain jurisdiction to hear and determine all matters arising from or related to the implementation, interpretation and/or enforcement of this order.

Dated: \_\_\_\_\_, 2010  
Wilmington, Delaware

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THE HONORABLE MARY F. WALRATH  
UNITED STATES BANKRUPTCY JUDGE