
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d) of
The Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported)

July 18, 2007

Cadence Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation)

001-33103

(Commission File Number)

41-2142317

(IRS Employer
Identification No.)

**12481 High Bluff Drive, Suite 200
San Diego, California 92130**

(Address of principal executive offices, including zip code)

(858) 436-1400

(Registrant's telephone number, including area code)

Not applicable

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 1.01 Entry into a Material Definitive Agreement

On July 18, 2007, Cadence Pharmaceuticals, Inc. (the “Company,” or “Cadence”) entered into a Development and Supply Agreement (the “Agreement”) with Baxter Healthcare Corporation (“Baxter”) for the completion of pre-commercialization manufacturing development activities and the manufacture of commercial supplies of the finished drug product for intravenous acetaminophen (“IV APAP”) for marketing by Cadence in the United States.

Pursuant to the terms of the Agreement, Baxter will receive development fees from Cadence upon the completion of specified development activities. In addition, Baxter will receive from the Company a set manufacturing fee based on the amount of finished IV APAP drug product produced, which prices may be adjusted by Baxter, subject to specified limitations. In addition, Cadence is obligated to purchase a minimum number of units each year following regulatory approval, or pay Baxter an amount equal to the per-unit purchase price multiplied by the amount of the shortfall. The Company is also obligated to reimburse Baxter for all reasonable costs directly related to work performed by Baxter in support of any change in the active pharmaceutical ingredient (“API”) source or API manufacturing process.

The Agreement also requires Cadence to fund specified improvements at Baxter’s manufacturing facility and purchase certain equipment for use by Baxter in manufacturing the finished IV APAP drug product. In January 2007, Cadence entered into an irrevocable standby letter of credit (“letter of credit”) in favor of Baxter in the amount of \$3,268,000, which was based on anticipated costs to be incurred by Baxter to facilitate the manufacturing of the finished IV APAP drug product. The letter of credit, which is collateralized by a certificate of deposit in the amount of \$1,634,000, may be drawn down in part or in whole by Baxter in the event that Cadence fails to perform its obligations to fund the specified facility improvements or equipment purchases.

For the first five years following regulatory approval of IV APAP, and subject to Baxter’s ability to timely supply the specified volumes required by Cadence, Baxter has the right to serve as sole supplier to Cadence for IV APAP for up to a certain number of units per year. Baxter also has a right of first refusal to supply quantities of IV APAP in excess of the specified number of units per year. However, if Baxter declines to supply such excess requirements, Cadence may purchase such requirements from a third party supplier. Baxter has agreed that, for the term and any renewals of the Agreement, neither it nor any of its affiliates will develop or commercially produce, for itself or for any third party, any intravenous formulation of a product containing acetaminophen for distribution or sale in the United States.

The Agreement has an initial term that terminates upon the five-year anniversary of the date of the first regulatory approval of IV APAP in the United States, and will automatically renew for successive one-year periods thereafter, unless either party provides at least two-year prior written notice of termination to the other party. In addition, either party may terminate the Agreement: (i) immediately, if approval of a new drug application for IV APAP is not received by a certain date, (ii) within 90 days, after written notice in the event of a material uncured breach of the Agreement by the other party, (iii) immediately, upon the filing of a petition of bankruptcy by the other party, or, (iv) immediately, if the parties are unable to reach agreement following good faith negotiations on certain matters. Cadence may also terminate the Agreement, effective 30 days after providing written notice, in the event that Baxter does not agree to the assignment of the Agreement by Cadence to a competitor of Baxter, subject to Cadence’s fulfillment of its minimum purchase requirement obligations under the Agreement.

If the Agreement is terminated, Cadence will pay Baxter for certain development activities performed by Baxter prior to the termination date, including all reasonable expenditures for facility improvements and purchases of capital equipment, including any non-cancelable expenditures outstanding as of the date of termination. Upon termination of the Agreement and subject to certain exceptions, the Company will purchase from Baxter all undelivered products manufactured or packaged under a purchase order from Cadence, at the price in effect at the time the purchase order was placed. Cadence is also obligated to reimburse Baxter for reasonable costs incurred in returning all Cadence-owned equipment, and for restoring Baxter’s manufacturing facility to its condition prior to the installation of the IV APAP-related improvements.

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The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by the Agreement, a copy of which is filed as Exhibit 10.1 to this current report on Form 8-K and its incorporated herein by this reference. The Company has requested confidential treatment on certain portions of the Agreement.

Item 9.01 Financial Statements and Exhibits

(d) *Exhibits.*

<u>Exhibit Number</u>	<u>Description of Exhibit</u>
10.1†	Development and Supply Agreement by and between Cadence Pharmaceuticals, Inc. and Baxter Healthcare Corporation.
†	Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from this report and submitted separately to the Securities and Exchange Commission.

SIGNATURES

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

CADENCE PHARMACEUTICALS, INC.

By: /s/ WILLIAM R. LARUE
 William R. LaRue
 Senior Vice President, Chief Financial Officer,
 Treasurer and Assistant Secretary

Date: July 23, 2007

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
10.1†	Development and Supply Agreement by and between Cadence Pharmaceuticals, Inc. and Baxter Healthcare Corporation.

† Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from this report and submitted separately to the Securities and Exchange Commission.

CERTAIN MATERIAL (INDICATED BY AN ASTERISK) HAS BEEN OMITTED FROM THIS DOCUMENT PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Confidential

DEVELOPMENT AND SUPPLY AGREEMENT

By and Between

CADENCE PHARMACEUTICALS, INC.

and

BAXTER HEALTHCARE CORPORATION

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EXHIBIT B	DEVELOPMENT PLAN (Section 4.1)
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EXHIBIT D	DEVELOPMENT FEE SCHEDULE (Section 4.1.4)
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EXHIBIT J	CONFIDENTIAL DISCLOSURE AGREEMENT (Sections 13.1)
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EXHIBIT L	DEFINITIONS (Section 2.0)

DEVELOPMENT AND SUPPLY AGREEMENT

This **DEVELOPMENT AND SUPPLY AGREEMENT**, (the “Agreement”) is effective as of July 18, 2007 (the “**Effective Date**”) between **CADENCE PHARMACEUTICALS, INC.**, a corporation organized and existing under the laws of the State of Delaware and having its principal office at 12481 High Bluff Drive, Suite 200, San Diego, CA 92130 (“**Cadence**”) and **BAXTER HEALTHCARE CORPORATION**, a corporation organized and existing under the laws of the State of Delaware and having its principal office at One Baxter Parkway, Deerfield, Illinois 60015 (“**Baxter**”). All references to “Cadence” and “Baxter” will include their respective Affiliates.

1.0 BACKGROUND

Cadence has an exclusive license to rights in the United States and Canada to a particular intravenous formulation and manufacturing process of the Compound, (collectively the “**Formulation**”). Cadence is seeking a contract manufacturing organization that is capable of producing the Formulation in a market-ready form as the Product, suitable for marketing in the Territory. Cadence currently plans to market the Product in the Territory.

Baxter manufactures and markets sterile products in glass containers for parenteral administration of pharmaceutical preparations. Baxter is interested in providing sterile product manufacturing services to Cadence.

Cadence and Baxter entered into a Letter of Intent dated November 27, 2006, as amended (collectively, the “LOI”), to establish their intent to enter into this Agreement, and the terms upon which both Parties would begin purchasing certain capital equipment, in addition to Baxter commencing certain technology transfer-related activities prior to the execution of this Agreement. Upon the Effective Date, the LOI is superseded in its entirety by this Agreement.

THEREFORE, the Parties, intending to be legally bound, agree as follows:

2.0 DEFINITIONS

Certain capitalized terms used in this Agreement and not otherwise defined herein have the meanings assigned to them in Exhibit L.

3.0 COOPERATIVE ORGANIZATION

In order to facilitate collaboration between the Parties to achieve the objectives of this Agreement, the Parties agree to the following organizational provisions:

3.1 Team Leader. Baxter and Cadence will each identify an individual(s) with appropriate authority to serve as the primary contact with the other Party about the Product and

the Parties' relationship under this Agreement (each a "Team Leader"). Baxter will identify a Team Leader for the Development Program, and a Team Leader for the commercialization phase. Each Team Leader will be responsible for obtaining cooperation and input from other individuals within such Team Leader's organization whose expertise and ability may be required from time to time to maximize the potential for successful collaboration under this Agreement.

3.2 Team Leader Responsibilities. Without limiting the scope of the Team Leader's responsibilities, particular consideration will be given to key operational aspects of the relationship, including but not limited to (i) Product development, regulatory matters highlighted in the Development Plan (Exhibit B) and Regulatory Strategy (Exhibit C); (ii) transitioning team leadership responsibilities to a corresponding Team Leader once commercialization of the Product is undertaken, including such matters as Product manufacturing, quality and marketing considerations; (iii) coordinating manufacturing activities to launch the Product into the marketplace; (iv) reviewing the status of ongoing contractual commitments under the Agreement; and (v) identifying and implementing actions which would improve the value of the Product to customers and the Parties. The Team Leaders will develop a process and procedures to optimize communication and collaboration between the Parties in order to timely refine the Development Plan and Regulatory Strategy and achieve the objectives set forth therein. The Team Leaders will communicate regularly during the Term of the Agreement at mutually agreeable times, and when necessary hold meetings at mutually agreeable places, to review progress and the challenges and opportunities for effective collaboration under this Agreement. The Team Leaders will analyze issues that arise during the Development Program and subsequent commercialization of the Product and attempt to resolve any differences as to the most appropriate course of action. If the Team Leaders are unable to resolve any such differences, the matter(s) shall be escalated to the Senior Vice President, Manufacturing for Cadence and with respect to Baxter, for matters arising prior to release of the first commercial (salable) batch of Product to the Vice President, Project Management for Baxter's BioPharma Solutions' business and for matters arising or after release of the first commercial (salable) batch of Product to the Plant Manager at Baxter's facility in Cleveland, Mississippi (the "Senior Executives"). If the Senior Executives are unable to resolve any such differences, the matter shall be handled pursuant to Section 16.0 of this Agreement.

4.0 DEVELOPMENT PROGRAM

4.1 Development Plan. The Parties desire to collaborate and to mutually agree to a Development Program and an associated Development Plan, including without limitation, defining upfront requirements and design parameters. Each Party shall use Commercially Reasonable Efforts to timely accomplish the tasks that it is assigned under the Development Plan.

4.1.1 General. The activities and key milestones to occur during the Development Program include, but are not limited to, the following activities or topics: (i) technical feasibility assessment; (ii) formulation and analytical development; (iii) stability studies and Product batch production to support Regulatory Submissions; (iv) Regulatory Submissions, and (v) Regulating Groups' review and approval.

In general, during the Term of the Agreement, Cadence will be responsible for (i) providing technical information about the API, (ii) timely providing the API and applicable reference standards required for implementation of the activities described in the Development Plan, (iii) compliance with Regulatory Submission reporting requirements regarding manufacture and control of the API, and (iv) timely review, drafting and filing of all necessary submissions with Regulating Groups.

In general, during the Term of the Agreement, Baxter will be responsible for (a) conducting all development studies identified as a Baxter Development Deliverable in the Development Plan, (b) manufacturing Product for Regulatory Submissions and as otherwise provided in the Development Plan and pursuant to the Regulatory Strategy set forth as part of Exhibits B and C, respectively, (c) preparing those portions of necessary submissions with Regulating Groups consistent with Baxter's obligations under the Regulatory Strategy, (d) supporting Cadence in its efforts to obtain and maintain approval of the Regulating Groups to sell the Product in the Territory, and (e) supplying Cadence's Requirements.

4.1.2 Development Deliverables. Baxter will promptly disclose to Cadence during the Term of the Agreement, in English and in writing, all Baxter materials set forth in the Development Plan ("Baxter Development Deliverables") which include such interim progress reports agreed upon by the Parties. Cadence will promptly disclose to Baxter during the Term of the Agreement, in English and in writing, all Cadence materials set forth in the Development Plan ("Cadence Development Deliverables").

4.1.3 Additional Development Deliverables. If the Development Deliverables set forth in Exhibit B prove to contain insufficient Information for a Party to carry out its responsibilities under this Agreement, including information required for Cadence to obtain and maintain Regulating Group approval and registration of the Product in the Territory in accordance with Section 5.0 or to complete the FDA's Annual Report and similar reports required by other Regulating Groups in the Territory, or to obtain patent protection in accordance with Section 14.0, the Parties will in good faith negotiate an amendment of Exhibit B to include as a Deliverable the additional Information or activities which are necessary for such purpose. Such negotiations may arise by mutual consensus of the Parties or following the written request of either Party.

4.1.4 Development Fees.

4.1.4.1 General. Development Fees payable by Cadence to Baxter for the Baxter Development Deliverables are described in Exhibit D, together with payment milestones.

4.1.4.2 Additional Work. The activities described in Exhibits B and C are the basis for determination of the Development Fee. Baxter will not be required to perform, nor be entitled to reimbursement for, any work beyond that described in Exhibits B and C unless and until the Parties reach written agreement (coordinated through the Team Leaders under Section 3.2) on the scope of any additional work and the related additional expenses.

Notwithstanding the foregoing, if any tests, studies or other activities beyond those encompassed by Exhibits B and C are requested pursuant to Section 3.2 which are required for obtaining or maintaining approvals or registrations of the Product in the Territory, then such tests, studies or other activities will be conducted at Cadence's expense. To the extent Baxter assists Cadence in conducting such additional tests, studies or other activities, Cadence will pay Baxter a fee to be negotiated in good faith between the Parties. By way of example, additional development work might be required in response to Regulating Group requests during review of Regulatory Submissions (such as laboratory work or environmental assessment), additional tests to demonstrate compliance with other compendia, or country specific import testing requirements.

4.1.5 Letter of Credit. Prior to the Effective Date, Cadence has established for Baxter's benefit an irrevocable Letter of Credit in a face amount of Three Million Two Hundred Sixty Eight Thousand Dollars (\$3,268,000) in the form delivered and with Silicon Valley Bank (the "Letter of Credit"). The Letter of Credit shall secure Cadence's performance of its obligations to reimburse Baxter for costs associated with the equipment to be purchased and facility improvements outlined in Section 4.1.5.2 ("Baxter Capex"). In the event Cadence fails to perform its obligations as set forth in Section 4.1.5.2, Baxter may, in its sole discretion, draw down all or a portion of the Letter of Credit to satisfy such payment obligation. Baxter's remedy described in this paragraph shall be in addition to any other remedy described herein or under applicable law.

4.1.5.1 Reduction Process. On a calendar quarterly basis, beginning after the Effective Date, Cadence shall review invoices paid against items in the Baxter Capex for that quarter and provide Baxter with a letter indicating Cadence's intention to reduce the face value of the Letter of Credit, by amendment, for the total amount of the invoices paid in the prior periods (and not yet credited). If Baxter agrees with the amount of Cadence's proposed reduction, Baxter will send a letter to the designated contact of the issuer of the Letter of Credit authorizing the reduction, with a copy to Cadence. The issuance and maintenance of the Letter of Credit and its amendments will be at the sole cost and expense of Cadence. Any Letter of Credit amendments shall be in form and substance satisfactory to Baxter, and shall be implemented with no lapse in coverage.

4.1.5.2 Equipment Purchases and Facility Improvements. Cadence will fund certain facility improvements which are attached hereto as Exhibit E and incorporated herein by reference. The Parties shall mutually agree in writing to any expenditures relating to equipment purchases and facility improvements in excess of Three Million Two Hundred Sixty-Eight Thousand Dollars (\$3,268,000). At the end of each calendar quarter, Baxter shall provide Cadence with an invoice representing the costs of equipment purchases and facility improvements made by Baxter during the then calendar quarter. Cadence agrees to pay Baxter in accordance with Section 4.1.6.

4.1.6 Payment. Development Fees (under Section 4.1.4.1), authorized additional Development Fees (under Section 4.1.4.2), and costs for equipment purchases and facility improvements (under Section 4.1.5.2) will be paid by Cadence in United States dollars within thirty (30) days after the date of Cadence's receipt of each invoice from Baxter following

completion of the designated activities. Invoices not timely paid will be subject to a late payment charge of one and one-half percent (1-1/2%) per month, or the highest rate allowed by law if lower, until paid in full. If any portion of an invoice is disputed, then Cadence shall pay the undisputed amounts as set forth in the preceding sentence and the Parties shall use good faith efforts to reconcile the disputed amount within (60) days of receipt; provided, that Cadence shall not be obligated to pay any late payment fee on any such amount disputed in good faith.

4.2 Regulatory Strategy. Exhibit C sets forth Cadence's Regulatory Strategy associated with development of the Product. Cadence shall be solely responsible for the Regulatory Strategy, which must be finalized prior to commencement by Baxter of Product stability batch production; *provided*, Cadence will discuss with Baxter any elements of its Regulatory Strategy which may reasonably be expected to have an impact on Baxter's obligations under this Agreement.

4.3 Product.

4.3.1 Product Specifications. Exhibit A includes Product Specifications in provisional form as of the Effective Date of this Agreement and will be refined and agreed upon by the Parties prior to NDA stability batch production as part of the Development Program. The Quality Agreement shall govern the procedures for making changes to Product Specifications for commercial Product or in connection with further refinements of the Product. Cadence will be responsible for and must provide final approval of Product Specifications and Formulation Specifications and all changes thereto prior to implementation.

4.3.2 Label Copy. All label copy and changes therein, on the Product label itself and other label copy that Cadence uses to market Product in the Territory, will be the responsibility of Cadence. Any Product label affixed by Baxter to a Product shall be in the form most recently approved by Cadence.

4.4 Technical Issues. "Technical Failure" is defined as [***]. In the event there (i) is a Technical Failure, (ii) are technical issues that do not constitute a Technical Failure that arise during the Development Program, or (iii) the integration of the [***] equipment purchased by Cadence with respect to the Development Program has an adverse effect on the production process (including, but not limited to, the timing or cost of production) (an "Integration Failure"), the Parties will negotiate in good faith appropriate amendments to this Agreement, including without limitation, amendments to the Development Plan, to attempt to develop a technically feasible product.

5.0 PRODUCT REGISTRATIONS

5.1 Product Registration Application Ownership. Cadence will be the sole

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

owner of any registration applications submitted to Regulating Groups for the Product. Cadence will have responsibility for the documentation and submission of the registration applications to Regulating Groups for the Product in the Territory and for completing the FDA Annual Report and similar reports required by other Regulating Groups for Product, with support from Baxter in providing any information required from Baxter in order to complete such reports. Communications to and from the FDA and other Regulating Groups that involve the NDA or any other Regulatory Submissions to Regulating Groups for the Product are subject to the provisions of Section 5.4.

5.2 Product Registration in the United States.

5.2.1 Right of Reference – Drug Master File. Baxter acknowledges that it holds a Type III DMF (DMF Number[***]). Baxter will provide a Letter of Authorization for this Type III DMF to Cadence to support an intended proposal to conduct parametric release in lieu of end-product testing of the Product.

5.2.2 Additional Filing Data. During the Term of the Agreement, Baxter will, following prior written agreement with Cadence, provide the FDA and all other Regulating Groups in the Territory, with additional data and information related to the Product which are required for Cadence to obtain and maintain registration and approval of the Product in good standing in the Territory, including without limitation, Pre-Existing Specifications, Baxter Background Intellectual Property Rights and Original Product Data. Baxter reserves the right to inform the FDA and other Regulating Groups that such information is confidential and to advise the FDA and such Regulating Groups that Cadence will be entitled to reference such information on a confidential basis during the Term of the Agreement.

5.3 Communications to/from Regulating Groups. Baxter will promptly notify Cadence of any communication from or to the FDA, or any other Regulating Groups, in connection with the Product (collectively “Communications”), and Cadence will notify Baxter of Communications that are relevant to Baxter’s activities under this Agreement, and will use reasonable efforts to agree on (i) whether copies of such Communications and/or other Information should be provided to each other as additional Development Deliverables pursuant to Section 4.1.3; and (ii) which individuals need to collaborate on a response to Communications received. Cadence shall have primary responsibility to respond to all Communications. In the event that Baxter and Cadence are unable to agree on the foregoing items, then Cadence’s position will prevail as it pertains to all Communications sent to Regulating Groups relating to the API, Formulation, and the Product.

5.4 User Fees. Cadence will pay all user and/or filing fees charged to Cadence by Regulating Groups in the Territory which relate to the registration application and ongoing marketing of the Product, including, but not limited to, the Application Fee, the annual Drug Product Fee, and a portion of the Drug Establishment Fee.

6.0 COMMERCIAL SUPPLY

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

6.1 Supply and Purchase Obligations. Subject to Baxter’s ability to timely provide the specified volumes of the Product, during the first three Contract Years (as defined in Section 19.1) of this Agreement, Baxter will be sole supplier to Cadence in the Territory for the first [***] units of Product produced per Contract Year, and for Contract Years four (4) and five (5), Baxter will be the supplier for [***] units of Product produced per Contract Year, and Cadence will purchase from Baxter such purchase requirements of Product, for use or sale in the Territory (“**Requirements**”). For the purpose of this Section 6.1, “timely” shall mean that, within any consecutive [***] period, Baxter has delivered Product sufficient to cover [***] of Cadence’s firm purchase orders scheduled for delivery during that period.

6.1.1 Right of First Refusal. Cadence hereby grants to Baxter a right of first refusal for the supply of any units of Product in excess of [***] per Contract Year on the terms and conditions set forth in this Section 6.1.1. Cadence shall provide to Baxter, at least ninety (90) days in advance of the beginning of a Contract Year, notice of its requirements in excess of [***] units of Product for such Contract Year (“**Excess Requirements**”). Baxter shall have thirty (30) days following receipt of such notice to respond to Cadence in writing of its desire to supply all or any portion of the Excess Requirements. If Baxter declines to supply Cadence with all or any portion of the Excess Requirements or does not respond in writing to Cadence within such thirty (30) day period, Cadence shall be free to purchase the Excess Requirements from a third party supplier. Any Excess Requirements supplied hereunder shall be on the same terms and conditions as the Requirements for such Contract Year.

6.1.2 Minimum Purchase Requirement. During the Initial Term, Cadence shall purchase from Baxter a minimum of [***] units of Product per Contract Year Minimum Purchase Requirement”). These units will be ordered in the minimum batch size set forth in Exhibit F. If Cadence fails to purchase the Minimum Purchase Requirement in any Contract Year, within thirty (30) days after the end of each Contract Year, Cadence shall pay Baxter an amount equal to the amount per unit set forth in Exhibit F multiplied by the shortfall in units. Cadence shall not be obligated to pay any shortfall amount if Cadence’s failure to meet the Minimum Purchase Requirement is due to Baxter’s inability to timely supply Cadence with its Requirements of Product in the applicable Contract Year and Baxter’s inability to timely supply such Requirement is not due to Cadence’s failure to meet its obligations under this Agreement.

6.2 Forecasts. In order to assist Baxter in its production planning of Product for Cadence, Cadence will provide to Baxter, at least ninety (90) calendar days before the beginning of each calendar quarter commencing with the first Regulatory Submission to a Regulating Group in the Territory by Cadence for the Product and continuing thereafter during the Term of the Agreement rolling twelve (12) month forecasts of Cadence’s estimated Product requirements (“**Estimated Requirements**”) and expected monthly requirements for Product during such forecast period. Cadence will make such Estimated Requirements in good faith given market conditions and other information available to Cadence, but such Estimated Requirements shall not be binding on Cadence or Baxter except as provided in

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Section 6.3.

6.3 Firm Purchase Orders.

6.3.1 General. During the Term of the Agreement and upon the terms and conditions set forth in this Agreement, Baxter shall, or shall cause its Affiliates to, manufacture, or cause the manufacture of, and supply to Cadence Products, ordered pursuant to the process set forth in this Section 6.3, including, but not limited to volume variations and subject to the restrictions set forth herein. Cadence will place firm purchase orders for Product at least ninety (90) calendar days prior to the beginning of each calendar quarter and shall specify the ship dates for Product. Firm purchase orders will be placed in increments of no less than the minimum number of units of Product specified in Exhibit F, or such other number of units as then corresponds to the filling production lot sizes for Products. Subject to the provisions of Section 6.3.2, firm purchase orders will not be less than [***] percent ([***]%) nor more than [***] percent ([***]%) of Cadence’s Estimated Requirements of Product for the calendar quarter most recently updated. Notwithstanding the foregoing, Baxter will use Commercially Reasonable Efforts to comply with any of Cadence’s unplanned changes in firm purchase orders, but will not be held liable for its inability to do so. Subject to this Section, Sections 8.3, 12.2 and 17.1, Baxter will meet Cadence’s requested ship dates. Both Parties agree to work together to reduce lead time for orders and deliveries. Firm purchase orders will be made on such form of documentation as Baxter and Cadence agree from time to time, provided that the terms and conditions of this Agreement will be controlling over any terms and conditions included in any purchase order form used in ordering Product. Any term or condition of such purchase order form that is in addition to, different from or contrary to the terms and conditions of this Agreement will be void, unless the Parties otherwise agree by a separate written agreement.

6.3.2 Cancellation of Purchase Orders and Rescheduling. Cadence may cancel a firm Product purchase order or reschedule requested ship dates to a later date by giving Baxter prior written notice to such effect. Baxter will use reasonable efforts to comply with Cadence’s requests. If, however, either (i) a cancellation of a firm purchase order or (ii) a rescheduling of ship dates for a firm purchase order that causes a rescheduling by Baxter of the Product manufacturing date (“Cancellation/Rescheduling”), occurs prior to Baxter’s scheduled production date for such firm purchase order, Cadence will pay Baxter a cancellation fee or rescheduling fee (“Cancellation/Rescheduling Fee”) equal to the following amounts, based on the date of Cancellation/Rescheduling as follows:

<u>Number of Days prior to Baxter’s Scheduled Production Date</u>	<u>Cancellation/Rescheduling Fee payable</u>
More than sixty (60) days prior	[***]
More than thirty (30) days and less or equal to sixty (60) days prior	[***]
Less than or equal to thirty (30) days prior	[***]

6.4 Delivery; Shipment. All Product supplied under this Agreement will be

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delivered FCA Baxter's distribution site in Memphis. Baxter will make shipping arrangements with the appropriate carriers designated in writing by Cadence from the FCA point, under the agreements that Cadence has with those carriers. Accordingly, Cadence will be deemed the exporter of record for Product shipped outside of the United States (which should only occur to the extent such areas are included in the definition of "Territory.") Cadence warrants that all shipments of Product outside the United States will be in compliance with all applicable United States export laws and regulations, including the Export Administration Act, and all applicable import laws and regulations.

7.0 MANUFACTURING FEE

7.1 Manufacturing Fee. Baxter will invoice Cadence a Manufacturing Fee per unit of Product in the amount set forth in Exhibit F, upon release to finished goods inventory of Product that has been quality control released by Baxter in accordance with the chemistry, manufacturing, and controls (CMC) information for the Product, as provided by Baxter to support the NDA and Product Specifications set forth in Exhibit A, as may be amended from time to time. The Quality Agreement shall ultimately govern release of Product for delivery to Cadence.

7.2 Adjustments. Upon each annual anniversary of a Contract Year effective on the first day of the Contract Year, Baxter will increase the Manufacturing Fee by an amount equal to [***] per unit or [***], whichever is greater. Additionally, the Manufacturing Fee may also be adjusted to reflect increases in Baxter's cost of materials for the Product. Baxter will provide Cadence with written notice ninety (90) days prior to the effective date of any increase in the Manufacturing Fee, which notice shall set forth the amount and elements of such increase.

7.3 Additional Work and Fees. The Manufacturing Fee described in Section 7.1 is based upon the scope of activities that Baxter plans to undertake in the ordinary course to manufacture and release Product in accordance with the Product Specifications, Quality Agreement (Exhibit G) and other Exhibits. The Manufacturing Fee does not cover activities or expenses related to matters that might arise outside the ordinary course of manufacturing and releasing Product in accordance with the Product Specifications, Quality Agreement, and other Exhibits. By way of example only, additional work might be required for Product or process changes requested by the FDA or other Regulating Groups, API source changes or Manufacturing Process changes, USP or other regulatory requirements changes, excessive or untimely requests by Cadence for label changes or recalls or other actions by Regulating Groups, or mutually agreed upon expansion of the Territory. Baxter will not be required to perform, nor be entitled to reimbursement for, any such work until the Parties negotiate in good faith and reach written agreement on the scope of the additional work and the related additional expenses.

7.4 Payment; Late Payment Charges. Cadence will pay the Manufacturing Fee (under Section 7.1), expenses for additional work (under Section 7.3), maintenance-related costs (under Section 9.3), expenses associated with additional audits (under Section 10.9), expenses for labeling revisions (under Section 10.10.2) and costs associated with de-installation and restoration (under Sections 20.4, 20.5 and 20.6) and any other amounts owed to Baxter under this Agreement, in United States dollars within thirty (30) days after the date of Baxter's invoice, by wire transfer in United States dollars, to a bank account designated in writing by Baxter.

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Invoices not timely paid will be subject to a late payment charge of [***] per month, or the highest amount permitted by law, if lower. Notwithstanding the foregoing, should Cadence give Baxter a Deficiency Notice pursuant to Section 10.5, Cadence's obligation to pay under this Section 7.4 shall be suspended until the Parties have mutually agreed upon a resolution of the deviation(s) underlying any such Deficiency Notice.

8.0 API.

8.1 General. Cadence will, at its cost, supply API to Baxter at Baxter's manufacturing facilities designated in the Development Plan, or such other manufacturing facilities as the Parties may agree upon from time to time. API will be supplied timely, in adequate quantities to enable Baxter to meet its obligations to develop and manufacture the Product in accordance with the terms of this Agreement, all in conformance with the API Specifications set forth in Exhibit A, as may be amended by Cadence from time to time. Baxter and Cadence will agree on appropriate inventory levels for API and Product and Baxter will manage these inventory levels. Cadence will retain title to the API while it is in Baxter's possession. Baxter will not use the API supplied by Cadence for any purposes other than pursuant to the terms of this Agreement.

8.2 Change of API Source or API Manufacturing Process. Cadence will neither change its API source nor any API Manufacturing Process unless and until such change is approved by the FDA and all other Regulating Groups in the Territory for the Product. Cadence agrees to provide written notice to Baxter of any proposed change no later than Cadence's initial notice to the FDA or any other Regulating Group. Following such written notice to Baxter, Baxter will timely undertake work reasonably required to support Cadence's filings with the FDA and other Regulating Groups in the Territory to obtain approval for such change. Cadence will reimburse Baxter for all reasonable costs incurred by Baxter directly related to Baxter work performed in support of such API source or API Manufacturing Process change, including but not limited to the cost of new stability studies, submissions to the FDA and any other Regulating Groups and return of unused (if any) API from the prior source or manufactured under prior API Manufacturing Processes. Cadence will pay Baxter in accordance with Sections 4.1.4 and 4.1.6 if such change occurs during the development phase and Section 7.4 if such change occurs during the commercial phase. "API Manufacturing Process" is defined as a process used in the manufacture of API of such a type that a change in such process would require approval by the FDA or other Regulating Groups in the Territory in order to market, sell and distribute the Product in the Territory.

8.3 Risk of Loss of API. Subject to Section 12.2.1, Baxter will have the risk of loss or damage to the API from the time the API is delivered to Baxter's manufacturing facility and during the storage thereof. In the event of loss or damage to the API during such period, Baxter will immediately notify Cadence and Cadence will provide to Baxter API required for replacement thereof at the actual replacement cost of the API paid by Cadence to its supplier

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including duty, freight and testing costs. Cadence will provide to Baxter appropriate documentation evidencing such costs.

- 8.3.1** If the loss or damage occurred other than during the performance of the Normal Manufacturing Process, then Baxter shall pay Cadence for such replacement API in an amount equal to the actual cost paid by Cadence for such API, plus duty, freight and testing costs.
- 8.3.2** Per Section 8.4, if the loss or damage occurred during the performance of the Normal Manufacturing Process, the amount of API lost or damaged will be included in the annual yield loss calculation and a determination will be made at the end of the relevant Contract Year as to what amount, if any, is owed by Baxter to Cadence for such loss of API.
- 8.3.3** Notwithstanding the foregoing, Baxter shall not be required to pay Cadence to replace reasonable amounts of API that are consumed in the course of testing required for incoming receiving and inspection.
- 8.3.4** Baxter will pay amounts owed to Cadence under this Agreement, including without limitation amounts owed under Sections 8.3.1 and 8.3.2, in United States dollars within thirty (30) days after the date of Cadence's invoice, by wire transfer in United States dollars, to a bank account designated in writing by Cadence. Invoices not timely paid will be subject to a late payment charge of [***] per month, or the highest amount permitted by law, if lower.

8.4 Manufacturing Yield Losses. The actual yield loss percentage for each Contract Year shall be calculated, reconciled, and agreed to by Cadence and Baxter within forty-five (45) days following the end of the Contract Year. Baxter will be responsible for calculating actual yield loss percentage as per the methodology set forth in Exhibit H which is being provided for illustrative purposes. The Parties acknowledge and agree that any and all losses occurring other than during the performance of the Normal Manufacturing Process or any loss due to improper handling, storage or due to any negligence on the part of Baxter will not be included in the annual yield loss calculation, but will be reimbursed to Cadence in accordance with Section 8.3.1.

9.0 EQUIPMENT

9.1 Baxter Owned Equipment and Risk of Loss. All equipment supplied, owned or purchased by Baxter, including equipment purchased by Baxter and paid for by Cadence as set forth in Exhibit E ("Baxter Owned Equipment") shall at all times remain the property of Baxter and Baxter assumes the risk of loss of such property. Baxter hereby waives any and all rights of recovery against Cadence, or against its directors, officers, employees,

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agents or representatives, for any loss or damage to Baxter Owned Equipment, except if such loss or damage is caused by Cadence's gross negligence or willful misconduct.

9.2 Cadence Owned Equipment and Risk of Loss. All equipment supplied, owned or purchased by Cadence as set forth in Exhibit K ("Cadence Owned Equipment") shall at all times remain the property of Cadence and Cadence assumes the risk of loss of such property. Cadence hereby waives any and all rights of recovery against Baxter, or against its directors, officers, employees, agents or representatives, for any loss or damage to Cadence Owned Equipment, to the extent the loss or damage is covered or could be covered by insurance (whether or not such insurance is described in this Agreement), except if such loss or damage is caused by Baxter's gross negligence or willful misconduct. Baxter will use Cadence Owned Equipment only for activities directly related to development and commercialization of Product under this Agreement, except as otherwise agreed to in writing by Cadence.

9.3 Maintenance-related Costs of Baxter Owned Equipment and Cadence Owned Equipment. Baxter shall be responsible for maintaining the Cadence Owned Equipment consistent with its practices as in effect from time to time with respect to Baxter's manufacturing equipment. Baxter shall be responsible for all maintenance-related costs for Baxter Owned Equipment. Baxter shall be responsible for labor-related costs associated with the routine maintenance of Cadence Owned Equipment. For Cadence Owned Equipment, Cadence shall be responsible and reimburse Baxter for all costs other than such labor-related routine maintenance costs, including without limitation, the costs associated with the purchase of spare parts, any labor-related costs incurred by a third party and costs associated with extraordinary maintenance so long as such extraordinary maintenance is not caused by Baxter's failure to provide adequate routine maintenance, or Baxter's gross negligence or willful misconduct.

10.0 QUALITY MANAGEMENT

10.1 Quality Agreement; Compliance with laws. Baxter and Cadence shall, as soon as possible after the Effective Date but in all events within ninety (90) days following the Effective Date, in good faith negotiate and execute a Quality Agreement concerning the Product and covering the appropriate activities under this Agreement. Upon execution and delivery of the Quality Agreement by both Cadence and Baxter, the Quality Agreement shall automatically become part of this Agreement, as Exhibit G. In the event of a conflict between this Agreement and the Quality Agreement with respect to any provisions that specifically relate to quality assurance matters, the Quality Agreement shall govern or supersede. For clarity purposes, in the event of a conflict between this Agreement and the Quality Agreement with respect to all other matters, this Agreement shall govern or supersede. In performing their obligations under this Agreement, Baxter and Cadence shall comply with any and all applicable provisions of the Quality Agreement and with all applicable laws, rules and regulations.

10.2 Changes to Product Specifications. Subject to Section 4.3, Cadence Product Specifications may not be amended, changed or supplemented by Baxter without the prior written consent of Cadence. Except as provided in Section 4.3, Cadence will give

Baxter not less than ninety (90) days advanced written notice of an intention to implement voluntary changes in Product Specifications initiated by Cadence so that the Parties can collaborate on a plan to implement any related changes required to meet such changed Product Specifications in a timely and cost-efficient manner. For Product Specification changes mandated by Regulating Groups, Baxter shall use Commercially Reasonable Efforts to expedite such changes upon the request of Cadence. The allocation of the cost of manufacturing and facility changes required as a result of a change in Product Specifications will be determined by agreement of the Parties on a case-by-case basis as provided in Section 4.1.4 if such change occurs during the development phase and Section 7.4 if such change occurs during the commercial phase. Baxter will provide Cadence with all information needed to amend the Product NDA and other Regulatory Submissions in the Territory as a result of any approved Product Specification change. Baxter will continue to supply Cadence with Product approved under Cadence's existing NDA and other Regulatory Submissions until such time as the changed Product Specifications are permitted by each of the applicable Regulating Groups in the Territory, except as the Parties otherwise agree by separate written agreement.

10.3 Changes to Drug Product Manufacturing Process. Changes to the Drug Product Manufacturing Process (as defined below) will ultimately be governed by the Quality Agreement. Baxter will discuss any proposed changes to the Drug Product Manufacturing Process with Cadence and obtain approval for any associated change control plan prior to implementation of any development work to qualify the change. Baxter will follow its established procedures for changes which are made to its manufacturing process from Product mix to release and which relate to the manufacture of the Product ("Drug Product Manufacturing Process"). Baxter will notify Cadence of all such changes/revisions that require notice based on the Quality Agreement and Regulatory Documentation as provided to Baxter or such changes/revisions that could reasonably be expected to have a material effect on the Product. Baxter will obtain Cadence's written approval prior to making any such change or revision. Any such changes in the Drug Product Manufacturing Process will be done at Baxter's expense. Baxter will provide Cadence with all information needed to review and approve any changes and that are necessary to amend the Product NDA and other Regulatory Submissions in the Territory as a result of any approved Drug Product Manufacturing Process change. Baxter will continue to supply Cadence with Product approved under Cadence's existing NDA and other Regulatory Submissions until such time as the Product manufactured under the changed process is permitted by each of the applicable Regulating Groups in the Territory, except as the Parties otherwise agree by separate written agreement. Notwithstanding the foregoing, in the event any changes to the Drug Product Manufacturing Process are requested by Cadence, Baxter shall review the requested changes and Cadence shall obtain Baxter's written approval, prior to the implementation of any such changes. The costs associated with any changes to the Drug Product Manufacturing Process requested by Cadence shall be the responsibility of Cadence. All costs associated with any other changes to the Drug Product Manufacturing Process shall be mutually determined by the Parties.

10.4 Complaints and Adverse Event Reports. As between Baxter and Cadence, Cadence will be solely responsible for the reporting to Regulating Groups of adverse experiences with respect to the Product. Exhibit I sets forth certain specific provisions

regarding the handling of customer Product complaints and adverse experiences, including without limitation adverse event or reaction reports or FDA “field alerts”.

10.5 Non-Compliance of Product. Cadence will be responsible for reviewing batch documentation for each batch of Product and for providing Baxter with authorization to ship such Product batch. Cadence has the right to reject and return, at the expense of Baxter, all or any portion of any shipment of Products that deviates from the Product Specifications or cGMPs, without invalidating any remainder of such shipment. Cadence or its designated agent shall inspect the Products manufactured by Baxter upon receipt of such Products and related Certificate(s) of Analysis and shall give Baxter written notice (a “Deficiency Notice”) of all claims for Products that deviate from the Product Specifications or cGMPs within thirty (30) days after Cadence’s receipt of such Products and related Certificate(s) of Analysis (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, within thirty (30) days after discovery thereof by Cadence, but in no event after the expiration date of the Product). Should Cadence fail to provide Baxter with the Deficiency Notice within the applicable thirty (30)-day period, then the delivery shall be deemed to have been accepted by Cadence on the 30th day after delivery or discovery, as applicable. Except as set out in Section 15.2, Baxter shall have no liability for any deviations for which Cadence has failed to provide notice within the applicable 30-day period.

11.0 MARKETING

11.1 General. The Parties will cooperate in a reasonable manner to support and facilitate the sale of the Product in the Territory and communicate regularly to facilitate carrying out their respective responsibilities.

12.0 REPRESENTATIONS AND WARRANTIES

12.1 Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party that, as of the Effective Date (i) this Agreement is legal and valid and the obligations binding upon such Party are enforceable in accordance with their terms, subject to bankruptcy, insolvency, moratorium, reorganization or similar laws affecting the rights of creditors generally and the availability of equitable remedies, (ii) the execution, delivery and performance of this Agreement does not conflict with any agreement, instrument or understanding, oral or written, to which such Party may be bound, nor violate any law or regulation of any court, governmental body or administrative or other agency within the Territory having jurisdiction over it, and (iii) the Party owns, controls, or has the right to grant to the other Party the licenses and other rights to use the intellectual property it authorizes the other Party to use in carrying out the objectives of this Agreement and the Party is not aware of any restrictions, limitations or interests superior to the Party’s intellectual property rights which would prevent the other Party from using such intellectual property in carrying out the objectives of this Agreement or which would cause the other Party to infringe the rights of others. During the Term of the Agreement, if a Party becomes aware of any events or circumstances that are reasonably likely to cause its representations and warranties to be untrue, the Party will promptly provide the other Party with written notice of such events or circumstances, including details

reasonably requested by the other Party in order to evaluate the impact of such events or circumstances on this Agreement.

12.2 Warranties of Cadence.

12.2.1 API.

12.2.1.1 General. Cadence represents, warrants and covenants that the API, when delivered to Baxter hereunder, will, to the best of its knowledge after due inquiry (i) be manufactured, tested, and packaged in accordance with applicable cGMP regulations and all applicable laws and regulations of the FDA and other applicable Regulating Groups in the Territory; (ii) meet the API Specifications; (iii) not be adulterated or misbranded within the meaning of the FD&C Act or any similar laws or regulations of applicable Regulating Groups in the Territory; and (iv) not be an article which may not be introduced into interstate commerce under the FD&C Act or any similar laws or regulations of applicable Regulating Groups in the Territory. Cadence warrants that the Cadence Owned Equipment (as set forth in Exhibit K) will perform according to its specifications when operated by Baxter personnel according to documented procedures and the integration of the Cadence Owned Equipment will not have an adverse impact on the Development Program.

12.2.1.2 Replacement.

(a) In the event of non-acceptance by Baxter of any delivery of API due to its failure upon inspection or testing by Baxter to meet Cadence's warranties set forth in Section 12.2.1.1, Cadence's sole obligation and Baxter's exclusive remedy will be limited to replacement of the API (subject to the provisions of this Section).

(b) If, however, the failure of API to meet Cadence's warranties is not discoverable upon reasonable physical inspection and testing, but is identified by Baxter after storage and handling by Baxter in accordance with the Product labeling and after activities utilizing API have commenced under the Development Plan, then Cadence's obligation will also include payment to Baxter of an amount comparable to the Development Fees under Section 4.1.4 attributable to the development activities that Baxter must repeat with non-defective API, or if during the commercialization phase, after manufacturing activities utilizing API have commenced, payment to Baxter of the Manufacturing Fee per unit of Product required to be replaced using non-defective API.

(c) Following notice from Baxter and at the direction of Cadence, Baxter will return the then remaining defective API or Product that incorporates defective API or is otherwise non-compliant to Cadence or, at Baxter's option or if requested by Cadence, destroy the same or deliver it to a third party qualified in such waste disposal. Cadence will bear the cost of any return of API, Product or work-in-process, including freight and handling, and the costs of API, Product and/or work-in-process destruction, if requested by Cadence. Cadence will, at its expense, replace defective API as expeditiously as possible and pay Baxter for Product and work-in-process incorporating defective API within thirty (30) days of receipt of Baxter's detailed invoice following completion of the designated return or destruction hereunder.

12.3 Warranties of Baxter.

12.3.1 General. Baxter represents, warrants and covenants that Product manufactured under this Agreement, at the time of release at Baxter's manufacturing facility (i) will be manufactured, tested, and packaged in accordance with this Agreement, the Quality Agreement, applicable cGMP regulations and all other applicable laws and regulations of the FDA and other applicable Regulating Groups in the Territory; (ii) will meet the Product Specifications; (iii) will not be adulterated or misbranded within the meaning of the FD&C Act or any similar laws or regulations of applicable Regulating Groups in the Territory; and (iv) will not be an article which may not be introduced into interstate commerce under the FD&C Act or any similar laws or regulations of applicable Regulating Groups in the Territory. Notwithstanding the foregoing, this warranty will not extend to the API or the Formulation, nor to Product labeling, and will not apply to the extent Cadence has breached its warranty under Section 12.2.1.1.

12.3.2 Facility. At all times during the Term of the Agreement, Baxter shall (i) perform Baxter's obligations under this Agreement in compliance with all applicable cGMP regulations and all other applicable laws and regulations of the FDA and other applicable Regulating Groups in the Territory; (ii) use Commercially Reasonable Efforts to protect and maintain the Cadence Owned Equipment; and (iii) maintain sufficient expertise, with respect to personnel and equipment, to fulfill the obligations of Baxter established hereunder.

12.3.3 Product. Baxter represents, warrants and covenants that (i) Baxter or its Affiliate shall transfer to Cadence good and marketable title to the Products free from any and all liens, mortgages or encumbrances of any kind; (ii) all Product manufactured and supplied to Cadence under this Agreement shall have a shelf life of no less than [***]; and (iii) Baxter shall use Commercially Reasonable Efforts to supply Product under this Agreement with a shelf life of no less than [***]. Such shelf life shall be measured against the month of expiration that is imprinted on the label at the time of manufacture. Baxter further represents, warrants and covenants that all batches of the Product shall be made available by Baxter for pick-up by Cadence or its designee promptly. For purposes of this Section 12.3.3, "date of its release" shall mean the date the Product is approved by Baxter quality control as evidenced by the issuance of a certificate of compliance.

12.3.4 Debarred Persons. Baxter covenants that it will not in the performance of its obligations under this Agreement use the services of any person debarred or suspended under 21 U.S.C. §335(a) or (b).

12.3.5 Cadence Licensed Intellectual Property. Baxter acknowledges and agrees that (A) it has been informed that Product is to be made subject to the Cadence Licensed Intellectual Property, and (B) that it will only manufacture Product for the benefit of Cadence and its sublicensees.

12.3.6 Replacement. Baxter's sole obligation and Cadence's exclusive remedy for breach of Baxter's warranties set forth in Sections 12.3.1 through 12.3.4, other than if such breach is caused by the gross negligence or intentional misconduct of Baxter, will be

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limited to replacement of the Product and including reimbursement of Cadence's actual costs associated with any recall or marketing withdrawal of the Product. Following Baxter's notice to Cadence that additional API will be required to replace defective Product, Cadence will promptly provide to Baxter API necessary for replacement of such Product. Cadence will provide to Baxter appropriate documentation evidencing the actual replacement cost of the API paid by Cadence to its supplier including duty, freight and testing costs. Notwithstanding the foregoing, Baxter will pay no more for the additional API than Cadence's actual costs for the replacement API, plus duty, freight and testing costs.

12.4 Limitation of Warranties. NEITHER PARTY MAKES ANY OTHER EXPRESSED OR IMPLIED WARRANTY EXISTS, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND EACH PARTY EXPRESSLY DISCLAIMS ANY SUCH WARRANTIES. Except as provided in Section 15.0, or as otherwise expressly stated in this Agreement, neither Party will be liable to the other Party for any proximate, indirect, incidental or consequential damages arising from a breach of warranty under this Agreement.

13.0 CONFIDENTIALITY

13.1 Pre-Existing Confidentiality Agreement. The Parties have previously signed a Confidentiality Agreement effective April 11, 2006, a copy of which is attached to this Agreement as Exhibit J, to cover the exchange of confidential information and materials relating to [***].

13.2 Confidentiality. Any Confidential Information of the Parties exchanged hereunder shall be governed by, and shall be maintained in confidence pursuant to, the confidentiality provisions set forth in the Confidentiality Agreement.

13.3 Exceptions. In addition to the exceptions set forth in the Confidentiality Agreement, Cadence may provide a copy of this Agreement and all its exhibits and amendments to the licensors of the Cadence Licensed Intellectual Property, Bristol-Myers Squibb Company and SCR Pharmatop; *provided, however,* that Cadence will redact all terms related to confidential financial information, and shall request of such licensors of the Cadence Licensed Intellectual Property the ability to redact other terms as reasonably requested to be redacted by Baxter prior to providing such documents to licensors of the Cadence Licensed Intellectual Property.

13.4 Publicity and SEC Filings. The Parties agree that any public announcement of the execution of this Agreement shall only be by one or more press releases mutually agreed to by the Parties. The failure of a Party to return a draft of a press release with its proposed amendments or modifications to such press release to the other Party within five (5) days of such Party's receipt of such press release shall be deemed as such Party's approval of such press release as received by such Party. Unless the prior written consent of the other Party is obtained, no Party shall, except as may be required by law or regulations (including without limitation any United States Securities and Exchange Commission filings required) in any manner disclose or advertise or publish or release for publication any statement mentioning the other Party or information contained in or acquired pursuant to this Agreement, or the fact that any Party has furnished or contracted to furnish the other Party the items required by this Agreement, or quote

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the opinion of any employee of the other Party. In the event Cadence proposes to file with the Securities and Exchange Commission or the securities regulators of any state or other jurisdiction a registration statement or any other disclosure document which describes or refers to this Agreement under the Securities Act of 1933, as amended, the Exchange Act, or any other applicable law relating to securities matters, Cadence shall notify Baxter of such intention and shall provide Baxter with a copy of relevant portions of the proposed filing not less than five (5) Business Days prior to such filing (and any revisions to such portions of the proposed filing a reasonable time prior to the filing thereof), including any exhibits thereto relating to this Agreement, and shall use reasonable efforts to obtain confidential treatment of any information concerning this Agreement that Baxter requests be kept confidential, and shall only disclose Confidential Information which it is advised by counsel or the Securities and Exchange Commission is legally required to be disclosed. No such notice shall be required under this Section 13.4 and each Party may disclose any previously disclosed information if the substance of the description of or reference to this Agreement contained in the proposed filing or disclosure has been included in any previous filing made by either Party hereunder or otherwise approved by the other Party. Baxter may communicate to investors information to the extent made public by Cadence.

13.5 Survival. The obligations under this Section 13 will extend for the longer of the term of this Agreement or [***].

14.0 INTELLECTUAL PROPERTY

14.1 Ownership of Inventions.

14.1.1 Ownership of Background Intellectual Property Rights. Ownership of Background Intellectual Property Rights will remain in the Party owning them on the Effective Date of this Agreement.

14.1.2 Cadence Ownership. The entire right, title and interest in all discoveries, inventions and improvements which are conceived or reduced to practice during the course of the work being performed pursuant to this Agreement (i) solely by Cadence or its employees, agents or other representatives; or (ii) by Baxter or its employees, agents or other representatives (alone or jointly with one or more Cadence employees, agents or representatives) useful only in connection with the Compound, the Product and/or the Formulation (the "Cadence Inventions") will be owned solely by Cadence.

14.1.3 Baxter Ownership. The entire right, title and interest in all discoveries, inventions and improvements which are conceived or reduced to practice during the course of work being performed pursuant to this Agreement solely by Baxter or its employees, agents or other representatives, other than Cadence Inventions and Joint Inventions (the "Baxter Inventions") will be owned solely by Baxter, subject to Sections 14.2.2 and 14.3.

14.1.4 Joint Ownership. Subject to Sections 14.1.2 and 14.1.3, the entire right, title and interest in all discoveries, inventions and improvements which are conceived or

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reduced to practice during the course of the work being performed pursuant to this Agreement jointly by (i) Cadence or its employees, agents or other representatives and (ii) Baxter or its employees, agents or other representatives (the "Joint Inventions") will be jointly owned by Cadence and Baxter, each of which will own an undivided one-half (1/2) interest in such invention, subject to Sections 14.2.2 and 14.3. Each Party will cooperate with the other in completing any patent applications relating to Joint Inventions, and in executing and delivering any instrument required to assign, convey or transfer to each Party its undivided one-half (1/2) interest.

14.1.5 Assignment of Ownership Rights. All employees, consultants, subcontractors and agents performing services for a Party under this Agreement shall have assigned in writing to such Party all of their right, title and interest in, to and under any and all discoveries, inventions and improvements directly related to the Product so as to effectuate the provisions of this Article 14.

14.2 Reports: Information Developed During Project.

14.2.1 Content of Reports. Baxter will provide to Cadence reports containing the data, test results, and specifications or procedures for the Product developed specifically for the Compound and/or the Formulation ("API/Formulation Specifications"), all as described in detail under the heading "Reports" in the Development Deliverables set forth in Exhibit B. The Reports may also contain references to (i) pre-existing Baxter standard operating procedures, specifications, material codes and their specifications, and other information developed by Baxter prior to the execution of this Agreement, but not including any such procedures, specifications, material codes and their specifications or other information developed by Baxter in its Grosotto facility and which is owned or licensed to the licensor of Cadence Licensed Intellectual Property ("Pre-Existing Specifications") that fall within Baxter Background Intellectual Property Rights and (ii) original laboratory notebooks and other Good Laboratory Practices documentation generated by Baxter or its agents pursuant to this Agreement ("Original Product Data.").

14.2.2 Ownership of Reports and Contents. The Reports, the Original Product Data solely as it relates to the Product, and the data, test results, and API/Formulation Specifications therein, will become the property of Cadence and will be treated as Cadence's Confidential Information and be subject to the provisions of Section 13.0 of this Agreement. For the avoidance of doubt, the Reports, data, test results and API/Formulation Specifications will become the property of Cadence even if they constitute Baxter Inventions under Section 14.1.3 or Joint Inventions under Section 14.1.4, subject to the Cadence Product License granted to Baxter under Section 14.3.1. Pre-Existing Specifications, Baxter Background Intellectual Property Rights, as well as Original Product Data (other than as it relates to the Product), will remain the property of Baxter and will constitute Baxter's Confidential Information and be subject to the provisions of Section 13.0 of this Agreement, subject to the Baxter License under Section 14.3.2.

14.2.3 Archiving of Reports. In accordance with Section 10.11, Baxter will retain the original Reports and Original Product Data for archival purposes.

14.3 Licenses.

14.3.1 To Baxter From Cadence. Cadence hereby grants to Baxter a nonexclusive, royalty-free license, with a right to sublicense solely to a Baxter Affiliate, to make the Product in the Territory under Cadence Background Intellectual Property Rights, Cadence Licensed Intellectual Property, Cadence Inventions and Joint Inventions (the “**Cadence Product License**”), only to the extent necessary for Baxter to fulfill Baxter’s obligations under this Agreement. The Cadence Product License shall be subject and subordinate to the IV APAP Agreement and the Pharmatop License Agreement. BMS shall be an express third party beneficiary of Baxter’s obligations under the Cadence Product License that relate to compliance with the terms and conditions of the IV APAP Agreement with the express right to enforce the same directly against Baxter. Cadence shall provide Baxter with the text of any amendment or restatement of either the IV APAP Agreement or the Pharmatop License Agreement within fourteen (14) days after the effective date of such amendment or restatement; *provided, however*, that Cadence may redact the text to delete confidential information solely to the extent such confidential information does not alter the scope of either Party’s rights under this Agreement. The Cadence Product License shall terminate immediately upon the termination of the sublicense or license from BMS to Cadence with respect to such right, but Cadence must provide prompt notice of such termination to Baxter. Cadence shall indemnify Baxter against any claim of infringement, misappropriation or unauthorized use of Cadence Licensed Intellectual Property to the extent such claim arises from Baxter’s use of Cadence Licensed Intellectual Property after termination of the Cadence Product License but before Baxter received actual notice of such termination.

14.3.2 To Cadence From Baxter. Baxter hereby grants to Cadence (a) a nonexclusive, royalty-free, license in the Territory, with a right to sublicense to Cadence Affiliates, licensors of Cadence Licensed Intellectual Property and, with Baxter’s prior written consent, not to be unreasonably withheld, conditioned or delayed, Cadence sublicensees, to make, have made, use, sell, offer for sell and import the Product under Baxter Background Intellectual Property, only to the extent that such Baxter Background Intellectual Property is actually used in the manufacture of the Product under this Agreement; and (b) an exclusive, royalty-free, worldwide license, with a right to sublicense to Cadence Affiliates, licensors of Cadence Licensed Intellectual Property and, with Baxter’s prior written consent, not to be unreasonably withheld, conditioned or delayed, Cadence sublicensees, to make, have made, use, sell, offer for sale and import the Product under all Baxter Inventions and Baxter’s interest in all Joint Inventions, each only to the extent actually used in connection with the Compound, the Product and/or the Formulation (collectively (a) and (b) of this Section 14.3.2 shall be known as the “**Baxter License**”). The license set forth in subsection (b) of the immediately preceding sentence shall be exclusive, even as to Baxter, only to the extent such Baxter Inventions and Joint Inventions are actually used in connection with the Compound, the Product and/or the Formulation. Baxter shall retain full rights to exploit such Baxter Inventions and Joint Inventions (i) for the purpose of performing its obligations under this Agreement and (ii) to the extent such Baxter Inventions and Joint Inventions are not used in connection with the Compound, the Product and/or the Formulation. The license set forth in subsection (b) hereof shall become nonexclusive, and all sublicenses under the Baxter License (except for sublicenses

to Cadence Affiliates and licensors of Cadence Licensed Intellectual Property) shall terminate, immediately upon the termination of this Agreement, the IV APAP Agreement or the Pharmatop License Agreement. Notwithstanding the foregoing, the Baxter License shall survive if this Agreement is terminated by Cadence pursuant to Sections 19.2.1.2 or 19.2.1.3.

14.3.3 Pre-Existing Specifications and Original Product Data. Baxter will (i) make Pre-Existing Specifications referenced in the Reports and Original Product Data available to Regulating Groups as directed by such Regulating Groups and as provided in Section 5.0, and (ii) upon Cadence's reasonable request, provide copies of Pre-Existing Specifications referenced in the Reports and relevant portions of Original Product Data (but excluding data or information which is unrelated to the Product) to Cadence for Cadence's use in Regulatory Submissions outside the United States if (a) pursuant to Section 5.0 such information is reasonably required for Cadence's Regulatory Submission for the Product in the Territory and (b) Cadence agrees to treat all such information (other than as it relates to the Product and which is owned by Cadence under this Agreement) as Baxter's Confidential Information under the provisions of Section 13.0.

14.4 Patents.

14.4.1 Patent Filings on Solely-Owned Inventions. Each Party will, in its sole discretion, prepare, file, prosecute and maintain Patent Applications for inventions as to which it has sole ownership under Sections 14.1 and 14.2 above and will be responsible for related interference proceedings. Each Party will endeavor to ensure whenever possible that claims are filed and prosecuted in such Patent Applications specifically directed to the Field. At least thirty (30) days prior to the contemplated filing date, each Party responsible for preparing a Patent Application will submit to the other Party a substantially completed draft of such Patent Application. Each Party will bear all costs under this Section for inventions as to which it has sole ownership. Each Party will cooperate with the other Party's perfection of filings.

14.4.2 Joint Inventions and Patent Filings. With respect to all Patent Applications on Joint Inventions ("Joint Patent Applications"), Baxter will prepare and file Joint Patent Applications and will diligently prosecute and maintain same. At least thirty (30) days prior to the contemplated filing, Baxter will submit a substantially completed draft of all such Joint Patent Applications to Cadence for its approval. As to claims contained in any Joint Patent Application directed to the Field, Cadence shall have the right to comment and to have any such reasonable comments incorporated into the claims included in such Joint Patent Application prior to filing. If the parties are unable to resolve any differences regarding the claim language directed to the Field, the matter will be handled pursuant to Section 16.0 of this Agreement. As to claims contained in any Joint Patent Applications directed outside the Field, Baxter will confer with Cadence and shall in good faith consider adopting Cadence's suggestions regarding the prosecution of such claims included in the Joint Patent Applications after taking into account the interests of Cadence and its licensors and sublicensees under the Joint Patent Applications. The Parties will share equally the costs of the preparation, filing, prosecution and maintenance of any Joint Patent Applications and will share equally the costs of any related interference proceedings. Baxter will copy Cadence with any official actions and submissions in such Joint Patent Applications. If either Party elects not to pay its portion of any shared costs for a Joint Patent

Application, the other Party may proceed with such Joint Patent Application in its own name and at its sole expense, in which case the Party electing not to pay its share of costs will assign its entire right, title and interest in and to such Joint Patent Application to the other Party. Any such election and related assignment shall be on a jurisdiction-by-jurisdiction basis.

14.4.3 Public Disclosure. Each Party agrees to delay any public disclosure of the subject matter of any Patent Application until after filing of such Patent Application, but in no event less than one hundred eighty (180) days after notice to the other Party of the intent to disclose such subject matter.

15.0 INDEMNIFICATION

15.1 Indemnification By Cadence. Cadence, on its own behalf, and on behalf of its Affiliates, will defend, indemnify and hold harmless Baxter and its Affiliates, and their respective directors, officers, shareholders, employees and agents, and each of their successors and permitted assigns, from and against any and all third party claims, actions, causes of action, liabilities, losses, damages, costs or expenses, and resulting settlements, awards or judgments, including reasonable attorneys' fees ("**Damages**"), which arise out of or relate to (i) the failure of API provided by Cadence hereunder to meet the warranties set forth in Section 12.2.1; (ii) a breach by Cadence of any of its other representations, warranties, covenants, agreements or obligations under this Agreement; (iii) the negligence or willful misconduct of Cadence in the performance or nonperformance of any of Cadence's obligations under this Agreement; (iv) personal injury or property damage caused by the Product at any time before or after first commercial sale (except to the extent covered by Baxter's indemnification obligations set forth in Section 15.2); or (v) any patent, trade name, trademark, service mark or copyright infringement, or any claim or judgment of such infringement thereof, relating to the Formulation or API supplied by Cadence, or to the Product (except to the extent covered by Baxter's indemnification obligations pursuant to Section 15.2), or the intellectual property licensed to Baxter under Section 14.3.1, or the use or printing of any trademark(s), trade names or copyrightable materials of Cadence or its Affiliates, as authorized by this Agreement.

15.2 Indemnification By Baxter. Baxter, on its own behalf, and on behalf of its Affiliates, will defend, indemnify and hold harmless Cadence and its Affiliates, and their respective directors, officers, shareholders, employees and agents, and each of their successors and permitted assigns, from and against any and all Damages which arise out of or relate to (i) the failure of Product provided by Baxter hereunder to meet the warranties set forth in Section 12.3; (ii) a breach by Baxter of any of its other representations, warranties, covenants, agreements or obligations under this Agreement; (iii) the negligence or willful misconduct of Baxter in manufacturing Product or in the performance or nonperformance of any of Baxter's obligations under this Agreement; or (iv) any patent, trade name, trademark, service mark or copyright infringement, or any claim or judgment of such infringement thereof, relating to the manufacturing processes or equipment used by Baxter to manufacture the Product (excluding the Cadence Owned Equipment (as set forth in Exhibit K) and further except to the extent covered by Cadence's indemnification obligations pursuant to Section 15.1), or the intellectual property licensed to Cadence under Section 14.3.2, or the use of any trademark(s), trade names or

copyrightable materials of Baxter or its Affiliates, as authorized by this Agreement.

15.3 Notice; Procedure. The indemnified Party will give the indemnifying Party prompt written notice of any claim, proceeding or suit for which it seeks indemnification under Sections 15.1 or 15.2 (hereafter, a “Matter”). The indemnifying Party will have fifteen (15) business days after receipt of the indemnified Party’s notice to notify the indemnified Party that the indemnifying Party elects to conduct and control the defense of such Matter. If the indemnifying Party does not give the foregoing notice, the indemnified Party will have the right to defend or settle such Matter in the exercise of its exclusive discretion, and the indemnifying Party will, upon request from the indemnified Party, promptly pay to it in accordance with Sections 15.1 or 15.2, as the case may be, the amount of any Damages resulting from such Matter. Except in the event of a conflict of interest between the indemnified Party and the indemnifying Party, if the indemnifying Party gives the foregoing notice, the indemnifying Party will have the obligation to undertake, conduct and control, through counsel of its own choosing and at the sole expense of the indemnifying Party, the conduct and control of the defense and any settlement of such Matter and the indemnified Party will cooperate with the indemnifying Party in connection therewith; provided that: (a) the indemnifying Party will not thereby permit any lien, encumbrance or other adverse charge upon any asset of the indemnified Party; (b) the indemnifying Party will permit the indemnified Party to participate in the defense or settlement through counsel chosen by the indemnified Party, but the fees and expenses of such counsel will be borne by the indemnified Party except as provided in clause (c) below; (c) the indemnifying Party will agree to reimburse promptly under Sections 15.1 or 15.2, as the case may be, the indemnified Party for the full amount of any liabilities, losses, damages, costs and expenses, including reasonable attorney” fees, resulting from the Matter, except for any fees and expenses of counsel for such indemnified Party incurred after the assumption of the conduct and control of such Matter by the indemnifying Party; and (d) the indemnifying Party will not settle or otherwise resolve any Matter without prior notice to the indemnified Party and the consent of the indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). So long as the indemnifying Party is contesting any Matter in good faith, the indemnified Party will not pay or settle any such Matter; except that such indemnified Party will have the right to pay or settle any such Matter but in so doing such indemnified Party will be deemed to have waived any right to indemnity therefore by the indemnifying Party under Section 15.1 or 15.2, as the case may be.

In the event that the indemnified Party reasonably believes that there exists a substantial conflict of interest with the indemnifying Party, then the indemnified Party will give the indemnifying Party notice of such conflict of interest and the indemnifying Party will not have the right or obligation to undertake, conduct and control the defense or settlement of any Matter and the indemnified Party will have the right to defend or settle such Matter in the exercise of its exclusive discretion; provided that the indemnifying Party (a) will not thereby permit any lien, encumbrance or other adverse charge upon any asset of the indemnified Party; and (b) will not settle or otherwise resolve any Matter without prior notice to the indemnified Party and the consent of the indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). In such event, the indemnifying Party will, upon request from the indemnified Party, promptly pay to it in accordance with Section 15.1 or 15.2, as the case may be, the amount of any liabilities, losses, damages and expenses, including reasonable attorneys’ fees, resulting from such claim, proceeding or suit.

15.4 No Claim for Losses. In no event will either Party or their respective Affiliates be liable for any special, indirect, incidental or consequential damages arising out of this Agreement.

15.5 Insurance. Baxter is self-insured for the types of liabilities for which indemnification by Baxter is likely to arise under Section 15.2. Prior to commercial launch of the Product, Cadence will obtain and keep in force at its sole expense during the Term of the Agreement, the following insurance covering Cadence and its agents, employees, representatives and subcontractors: (i) Comprehensive or Commercial General Liability in an amount not less than [***] dollars (\$[***]) each occurrence combined single limit for bodily injury and property damage for products completed operations (including vendors coverage), blanket contractual liability, personal injury and independent contractors protective insurance, which name Baxter as an additional insured and require at least thirty (30) days written notice to Baxter prior to any cancellation, non-renewal or material change in coverage. Cadence will provide Baxter with a certificate of insurance evidencing compliance with this insurance obligation.

16.0 ALTERNATE DISPUTE RESOLUTION

The Parties will attempt to settle any claim or controversy arising out of this Agreement through good faith negotiations and in the spirit of mutual cooperation. Any issues that cannot be resolved by the Senior Executives as set forth in Section 3.2 or any other issues between the Parties will be referred to the Chief Executive Officer of Cadence and the General Manager of Baxter's BioPharma Solutions business (the "Executive Officers") to resolve the dispute. In the event such Executive Officers cannot resolve the dispute, the dispute will be mediated by a mutually acceptable mediator to be chosen by the Parties within thirty (30) days after written notice by the Party demanding mediation. Neither Party may unreasonably withhold consent of the selection of the mediator and the Parties will share the costs of the mediation equally. The Parties may agree to replace mediation with some other form of Alternative Dispute Resolution "ADR", such as neutral fact-finding or a mini-trial. Any dispute which cannot be resolved by the Parties through mediation or another form of ADR within one hundred and ninety (90) days of the date of the initial written demand for mediation may then, and only then, be submitted to the Federal or state courts, as appropriate, for resolution. Nothing in this Section will prevent either Party from resorting to judicial process if (i) good faith efforts to resolve the dispute under these procedures have been unsuccessful or (ii) injunctive relief from a court is necessary to prevent serious and irreparable injury to one Party or to others.

17.0 FORCE MAJEURE

17.1 General. Neither Party will be liable, or deemed in breach of its obligations under this Agreement, for a delay in performance or nonperformance as the result of an act of governmental authority, war, acts of terrorism, riot, fire, explosion, hurricane, flood, strike, lockout, or injunction; inability to obtain fuel, power, raw materials, labor, Containers, plastic film or components, or transportation facilities; accident, breakage of machinery or apparatus

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solely to the extent not caused by such Party's negligence or willful misconduct; or any other cause beyond its reasonable control preventing the manufacture, shipment, or acceptance, of the Product, or any component thereof ("Force Majeure") provided that the affected Party (i) promptly notifies the other Party of the Force Majeure event as provided in Section 17.2, (ii) uses reasonable diligence and efforts to remedy the situation if reasonably capable of being remedied by that Party, (iii) continues performance of its obligations to the extent the Force Majeure event permits, and (iv) resumes performance of its obligations delayed by Force Majeure events as soon as possible. This requirement that any Force Majeure be remedied with all reasonable dispatch will not require settlement of strikes or labor controversies by acceding to the demands of the opposing parties in such strikes or labor controversies.

17.2 Notice. A Party affected by Force Majeure will promptly notify the other explaining the nature, details, and expected duration thereof. The affected Party will advise the other Party from time to time as to progress in remedying the situation and as to the time when the affected Party expects to resume its obligations and will notify the other Party as to the expiration of any Force Majeure as soon as the affected Party knows the date thereof. If a Party anticipates that a Force Majeure is reasonably likely to occur, that Party will notify the other Party as soon as practicable, explaining the nature, details, and expected duration thereof.

18.0 RELATIONSHIP OF THE PARTIES

It is expressly acknowledged and agreed that Baxter and Cadence will be independent contractors and that the relationship between the two Parties will not constitute a partnership, joint venture or agency. Neither Party, nor its agents or employees, will be deemed agents or representatives of the other Party. Neither Party will have the right to enter into any contracts or commitments in the name of or on behalf of the other Party, without the prior written consent of the other Party to do so. Nothing herein will be construed as granting any license or right under any patent or trademark right of either Party, by implication or otherwise, to the other except as expressly provided herein.

19.0 TERM AND TERMINATION

19.1 Term and Expiration. This Agreement will be effective as of the Effective Date and will terminate at the end of the 5th Contract Year ("Initial Term"), unless terminated earlier as herein provided ("Term of the Agreement"). "Contract Year" is defined as (i) the twelve (12) month period beginning with the month in which the first regulatory approval of the Product by a Regulating Group in the Territory (including price approval if applicable in the jurisdiction in the Territory) is received by Cadence and (ii) each successive twelve (12) month period.

19.1.2 Automatic Renewal. Upon expiration of the Initial Term, this Agreement will automatically renew thereafter for consecutive one (1) year terms on each successive annual anniversary of the Contract Year unless either Party, by not less than two (2) years prior written notice to the other Party, signifies by such notice its intention to terminate this Agreement upon the expiration of the applicable Contract Year. By way of clarification, if either Party desires that this Agreement terminate at the end of the Initial Term, the Party must give

written notice before the first day of the fourth Contract Year.

19.2 Early Termination

19.2.1 Termination by Either Party. Either Party may terminate this Agreement as follows:

19.2.1.1 effective immediately upon the giving of written notice, if approval of the Product's NDA is not received within [***] months from the Effective Date;

19.2.1.2 effective ninety (90) days after written notice given by the non-breaching Party of a material breach of this Agreement by the other Party, if such breach is not cured within ninety (90) days of receipt of such notice containing details of such breach (or such additional time as is reasonably necessary to cure such breach provided the breaching Party has commenced a cure within the ninety (90) day period and is diligently pursuing completion of such cure); or

19.2.1.3 effective immediately upon written notice given by the non-bankrupt Party, if the other Party files a petition in bankruptcy, or is adjudicated a bankrupt, becomes insolvent, makes an assignment for the benefit of creditors, is voluntarily or involuntarily dissolved, or has a receiver, trustee or other court officer appointed for its property.

19.2.1.4 effective immediately upon written notice by either Party to the other Party if the Parties are unable to reach agreement following good faith negotiations as described in Section 4.4, if there is a Technical Failure or an Integration Failure; provided, however, that termination under this Section 19.2.1.4 shall in no event be effective earlier than [***] from the Delivery Date.

19.2.2 Termination by Cadence. In the event that Baxter does not agree to the assignment by Cadence of this Agreement or any of Cadence's rights or obligations hereunder to a competitor (as such term is defined in Section 23.1.3, below) of Baxter, Cadence may terminate this Agreement, effective thirty (30) days after giving written notice to Baxter, subject to Cadence's fulfillment of its Minimum Purchase Requirement obligations as set forth in Section 6.1.2.

20.0 EFFECTS OF TERMINATION

20.1 Payments. Termination will not relieve or release either Party from making any payments which may be due and owing under the terms of this Agreement.

20.2 Pre-Commercial Activities. Without limiting the generality of Section 20.1, Cadence will pay Baxter for any Pre-Commercial Activities performed by Baxter (as defined under the LOI) prior to the effective date of termination hereunder, including all reasonable expenditures made by Baxter in accordance with the terms of this Agreement for facility improvements and purchases of capital equipment, including any non-cancelable expenditures

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which are outstanding as of the date of termination of this Agreement.

20.3 Disposal of API or Product. Upon termination of this Agreement, Baxter will promptly return all then remaining API to Cadence, or if requested by Cadence and at Baxter's option, destroy such API or deliver it for destruction to a third party qualified in such waste disposal. Return or destruction of API will be at Cadence's expense if termination of the Agreement arises under Section 19.2.1.1 (failure of Product NDA to timely issue). Return or destruction of API will be at the other Party's expense if termination is initiated by a Party pursuant to Sections 19.2.1.2 through 19.2.1.4 due to an act or omission of such other Party. Product shall be returned to Cadence promptly at Cadence's expense and Cadence shall take delivery of and pay for all undelivered Products that are manufactured and/or packaged pursuant to a Firm Order, at the price in effect at the time the Firm Order was placed; provided that no such payment shall be due from Cadence if this Agreement is terminated by Cadence pursuant to Section 19.2.1.2 or 19.2.1.3, including, but not limited to, termination for Baxter's failure to provide sufficient quantities Products in accordance with the Product Specifications and cGMPs; or failure to provide such Products in a timely manner. If Cadence is responsible for the expense of disposition of API, Product, or work-in-process, Cadence will pay Baxter all reasonable amounts due Baxter under this Section within thirty (30) days of receipt of Baxter's detailed invoice following completion of the designated return or destruction.

20.4 De-Installation Costs of Cadence Owned Equipment. Cadence shall be entitled to physical possession of the Cadence Owned Equipment. Cadence agrees to reimburse Baxter for all reasonable costs incurred in the de-installation of Cadence Owned Equipment which includes without limitation the removal, crating and transportation or shipping of Cadence Owned Equipment from Baxter's manufacturing facility to a location specified by Cadence.

20.5 Restoration Costs of Baxter's Facility. Cadence agrees to reimburse Baxter for all reasonable costs incurred in the restoration of Baxter's manufacturing facility to its pre-installation condition, as set forth in Section 20.6, including, the repair of any damage to the manufacturing facility caused by or resulting from the removal of the Cadence Owned Equipment, despite the exercise of reasonable care.

20.6 De-installation, Removal and Restoration Activities. The de-installation, removal and restoration activities shall be conducted in a manner that is not unreasonably disruptive to, and does not impose unreasonable burdens on Baxter or its operations at its manufacturing facility. Baxter shall provide Cadence with a written estimate of the cost of (i) such disassembly, crating and removal (ii) the disconnection of any and all connections to the Cadence Owned Equipment including without limitation electrical, air piping, conduits, dust collecting ducts, in a manner which preserves in all material aspects the integrity of the structures and fixtures of Baxter's facility, and (iii) the restoration of the facility to a "four wall" condition, including the repair of any damage to the facility, which despite the exercise of reasonable care, was caused by or resulted from the removal of the machinery, equipment and any other fixed assets. Cadence shall be responsible for arranging for all transportation and shipping of the Cadence Owned Equipment being transferred from Baxter's facility to Cadence's location, including the timely application in its own name of any required licenses, permits or any other governmental authorization required to transfer the Cadence Owned Equipment.

20.7 Technology Transfer. Upon the request of Cadence at any time during the Term of the Agreement, Baxter shall cooperate in the technology transfer of the manufacture of the Products to a third-party supplier/manufacturer selected by Cadence in its sole discretion. In furtherance of the technology transfer, Baxter shall make its employees and other internal resources reasonably available to Cadence and the designated third-party supplier/manufacturer and provide copies of all technology, documents, data and other information solely related to the Cadence Product License and the Baxter License. Any such third-party supplier/ manufacturer that Cadence may designate to manufacture the Products shall be required to sign a customary and appropriate confidentiality agreement with Baxter with respect to the nondisclosure and the appropriate and limited use of any Baxter Confidential Information transferred hereunder. With respect to all documents, data and other information provided in connection with this Section 20.7, (i) Baxter shall be responsible for the cost of providing a single copy only; and (ii) in addition to paper and other tangible copies, Baxter shall, upon Cadence's request, also provide to Cadence and/or the third-party supplier/manufacturer electronic copies of such documents, data and other information, provided, that, Baxter or its Affiliates have electronic copies thereof, and provided, further, that Baxter shall have no obligation to reformat or otherwise alter or modify any such electronic materials. Notwithstanding the foregoing, this Section 20.7 shall not be construed to give any other manufacturer, whether or not a competitor of Baxter, access to Baxter's manufacturing facility, information in Baxter's Drug Master File [***], or right of reference to the Drug Master File. Cadence shall reimburse Baxter for its reasonable costs associated with the transfer of technology contemplated by this Section 20.7. At the time of the requested technology transfer, Cadence and Baxter shall discuss the feasibility and costs associated with Baxter providing to Cadence, in connection with such technology transfer, access to Baxter employees or consultants to facilitate the technology transfer.

20.8 Baxter Non-Compete Obligation. Baxter hereby agrees that neither it nor any of its Affiliates shall develop or commercially produce for itself or for any Third Party any intravenous formulation of product containing the Compound for distribution or sale in the Territory during the term of this Agreement and any renewals hereof. At any time during the term of this Agreement, Cadence may inform Baxter of its intention to commence negotiation with third parties regarding distribution services to wholesale warehouses for Product in the Territory. In such event, Baxter shall have the non-exclusive right to negotiate with Cadence for such services; however, neither party shall be obligated to enter into such agreement and, until such time as Cadence and Baxter may enter into a definitive written agreement for such services, nothing herein shall be construed to prevent Cadence from entering into an agreement for such services with any third party.

20.9 Survival. Expiration or termination of the Agreement will not relieve the Parties of any obligation accruing prior to such expiration or termination, and the provisions of Sections 12.2.1.1 (Cadence Warranty regarding API), 12.3 (Baxter Warranties), 5.1 (Product Registration Application Ownership), and Sections 13.0 (Confidentiality), 14.0 (Intellectual Property), 15.0 (Indemnification), 20.0 (Effects of Termination), 21.0 (Notices), 22.0 (Export), and 23.0 (Miscellaneous) will survive the expiration or termination of the Agreement. Any expiration or termination of this Agreement will be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement prior to expiration or termination.

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21.0 NOTICES

All notices or other communications which are required or permitted under this Agreement will be in writing and deemed delivered at the time they are personally delivered, or on the business day next following the date of confirmed transmission when sent by facsimile, or two (2) business days after being sent by a nationally recognized overnight courier, and addressed as follows:

If to Baxter:

Baxter Healthcare Corporation
BioPharma Solutions
Route 120 and Wilson Road
Round Lake, Illinois 60073
Attention: General Manager
Fax No.: 847-270-3410

With a copy to:

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015
Attention: General Counsel
Fax No.: 847-948-2450

If to Cadence:

Cadence Pharmaceuticals, Inc.
12481 High Bluff Drive, Suite 200
San Diego, CA 92130
Attention: Senior Vice President, Pharmaceutical Development and Manufacturing
Fax No: 858-436-1401

With a copy to:

Cadence Pharmaceuticals, Inc.
12481 High Bluff Drive, Suite 200
San Diego, CA 92130
Attention: General Counsel
Fax No: 858-436-8510

22.0 EXPORT

Each Party will adhere to the United States Export Administration Laws and Regulations and will not export or re-export any technical data or Information received from the disclosing

Party or the direct product of such technical data or Information to any proscribed country listed in the United States Export Administration Regulations, unless properly authorized by the United States Government.

23.0 MISCELLANEOUS

23.1 Binding Effect; Assignment.

- 23.1.1. This Agreement will be binding upon and inure to the benefit of the Parties and their successors and permitted assigns.
- 23.1.2. Baxter may not assign this Agreement or any of its rights or obligations hereunder except with the written consent of Cadence, such consent not to be unreasonably withheld; provided, however, that Baxter may arrange for subcontractors to perform specific testing services arising under this Agreement without the consent of Cadence; provided, further, that Baxter shall provide advance notice of the name and function of any such subcontractor and shall ensure such subcontractor's adherence to the terms of this Agreement, including, but not limited to, the obligations of confidentiality set forth in Section 13.0.
- 23.1.3. Cadence may assign this Agreement or any of its rights or obligations hereunder, except to a competitor of Baxter, without approval from Baxter; provided, however, that Cadence shall give prior written notice of any assignment to Baxter, any assignee shall covenant in writing with Baxter to be bound by the terms of this Agreement and Cadence shall remain liable hereunder. For the purposes of this Section 23.1, "competitor" means [***].
- 23.1.4. Notwithstanding the foregoing provisions of this Section 23.1, either Party may assign this Agreement to any of its Affiliates or to a successor to, purchaser or licensee of all or substantially all of its business, provided that such assignee agrees in writing to be bound hereunder. For purposes of the foregoing, the phrase "all or substantially all of its business" shall mean, with respect to Cadence, the business of Cadence relating to the Product and not necessarily any other products to which Cadence may have rights.

23.2 Entire Agreement. This Agreement, together with its Exhibits (including without limitation the Confidentiality Agreement) and the Letter of Credit, contains the entire agreement between the Parties relating to the subject matter hereof and all prior written and verbal proposals, discussions, writings, and other understandings, by and between the Parties and relating to the subject matter, are superseded hereby, including the LOI. None of the terms of this Agreement will be deemed to be waived by either Party or amended, unless such waiver or amendment is in writing executed by both Parties and such writing recites specifically that it is a

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waiver of or an amendment to the terms of this Agreement.

23.3 Governing Law. This Agreement will be deemed to have been entered into in the State of New York and its interpretation and construction and the remedies for its enforcement or breach are to be applied pursuant to and in accordance with the laws of the State of New York without regard to the United Nations Convention on Contracts for the International Sale of Goods and without giving effect to any choice of laws rule that would cause the application of the laws of any jurisdiction other than the internal laws of the State of New York, to the rights and duties of the Parties.

23.4 Severability. In the event that any one or more of the provisions contained in this Agreement should be held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein will not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affect the substantive rights of the Parties. The Parties agree to replace any invalid provision or parts thereof by new provision(s) which closely approximate the economic and proprietary results intended by the Parties.

23.5 Waiver. The waiver by either Party hereto of any right hereunder or of a material breach by the other Party will not be deemed a waiver of any other right hereunder or of any other material breach by said other Party whether of a similar nature or otherwise.

23.6 Review with Counsel. Each Party agrees that it has had the opportunity to review this Agreement with its legal counsel. Accordingly, the rule of construction that any ambiguity in this Agreement is to be construed against the drafting Party will not apply.

23.7 Counterparts. This Agreement may be executed in two counterparts, by original or facsimile signature, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[Remainder of page intentionally left blank.]

IN WITNESS WHEREOF, the Parties have executed this Agreement by their duly authorized representatives as of the date first set forth above.

CADENCE PHARMACEUTICALS, INC.

BAXTER HEALTHCARE CORPORATION

By: /s/ Theodore R. Schroeder

By: /s/ Daniel Tasse

Name: Theodore R. Schroeder

Name: Daniel Tasse

Title: President and Chief Executive Officer

Title: GM — BPT

Date: July 13, 2007

Date: July 18, 2007

EXHIBIT A
API/FORMULATION SPECIFICATIONS
CONTAINER DESCRIPTION
PRODUCT SPECIFICATIONS

Product Definition Assumptions:

Formulation (for 100 mL)

***	***
***	***
***	***
***	***
***	***
***	***
***	***
***	***

Other Drug Product Specifications

***	***
***	***
***	***
***	***
***	***
***	***

“Container” as defined in this Agreement includes the following components

***	***
***	***
***	***
***	***

Packaging

***	***
***	***
***	***

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT A (cont)

Product Definition Assumptions(cont):

Sterilization release method. [*]**

Active Ingredient. The API (paracetamol, USP) will be provided by Cadence free of charge and in a format suitable for aqueous mixing unless otherwise agreed by Cadence and Baxter. All other excipients will be provided by Baxter, and their cost has been incorporated into the Unit Price provided below.

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EXHIBIT B
DEVELOPMENT PLAN
Cadence Development Activities

	<u>Initiation</u>	<u>Transfer</u>	<u>Implementation</u>	<u>Submission and Approval</u>
***	***	***	***	***
***	***		***	***

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EXHIBIT C

PROPOSED REGULATORY STRATEGY

Cadence IV APAP – Transfer to Cleveland, MS
PQA No. [***]

[***]

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[***]

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EXHIBIT D
DEVELOPMENT FEE SCHEDULE

One-time Technology Transfer/Stability Batch/Registration Activities:

All amounts in \$1000s

Activity	Expense	Program Phase			
		I	II	III	IV
***	***	***			
***	***		***		
***	***		***		
***	***		***		
***	***		***		
***	***		***		
***	***			***	
***	***				***
***	***				***
***	***				***
***	***	***	***	***	***

Timing of Development Program Payments. A total payment of [***] is required for development program expenses, portions of which would be due at the time of the completion of each of the following phases:

Phase I: Program initiation (signing of **Letter of Intent** or equivalent). Note: As of the Effective Date of this Agreement, the [***] Program initiation fee, also described as Phase I Development Activities, has been paid in full by Cadence.

Phase II: Activities leading up to formal scheduling of stability batch production

Phase III: Manufacture of stability batch

Phase IV: Submission of NDA

The Development program assumes the development of 2 container sizes (50 mL; 100 mL) in one type of glass. If a second glass type is required to be validated, total expenses and required payment would rise to [***]. The program time line would also be impacted.

* The expenses detailed in the Table above total [***], but a reduced payment of [***] has been requested by Baxter as an incentive to confine development activities to one glass type.

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EXHIBIT E

BAXTER FACILITY IMPROVEMENTS AND BAXTER OWNED EQUIPMENT

Facility Improvements and Capital Equipment Owned by Baxter:

Facility Build-Out and Upgrades to create dedicated IV-APAP line

[***]

[***]

Ancillary systems for mixing, sterilization, and packing

[***]

Installation costs, taxes, shipping costs

[***]

[***]

TOTAL

[***]

The preceding expenses are required for Baxter to create the IV-APAP production line and would be borne entirely by Cadence.

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EXHIBIT F

MINIMUM BATCH SIZES AND MANUFACTURING FEE

Minimum Batch Size:

The batch size on which all pricing is based is the optimal batch as determined by the Development Program. As of the Effective Date, the minimum batch size has not been determined. The parties agree that once the minimum batch size has been established by mutual agreement, all Product will be produced in the agreed upon batch size.

Manufacturing Fee Structure:

	<u>100 mL vial</u>
The first [***] units ordered	[***]
Units [***] to [***]	[***]
Units [***] to [***]	[***]
Units [***] to [***]	[***]
Units over [***]	[***]
	<u>50 mL vial</u>
The first [***] units ordered	[***]
Units [***] to [***]	[***]
Units [***] to [***]	[***]
Units [***] to [***]	[***]
Units over [***]	[***]

For the avoidance of doubt, in a year in which BAXTER accepts Cadence's Purchase Orders for [***] units of Product in the 100mL configuration, the first [***] units would be priced at \$[***], the next [***] at \$[***], the next [***] million at \$[***], the next [***] at \$[***], and the remaining [***] at \$[***].

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EXHIBIT G
QUALITY AGREEMENT
[TO BE ATTACHED AFTER THE EFFECTIVE DATE]

EXHIBIT H
COST OF API AND METHODOLOGY FOR CALCULATING MANUFACTURING
YIELD LOSSES

Description of Cadence Material, the Active Pharmaceutical Ingredient (API):	IV-APAP
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

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EXHIBIT I

ADVERSE EVENT HANDLING PROCEDURE

Each Party will notify the other Party following receipt of any information within the timeframes specified herein, including but not limited to information regarding any threatened or pending action by Regulating Groups, that might reasonably affect the safety or efficacy claims of the Product, activity under the Development Program, production or marketing of the Product, or the ability of Cadence to supply API. Promptly upon receipt of such notice, the Parties will consult with each other in an effort to arrive at a mutually acceptable procedure for taking appropriate action, *provided, however*, that nothing contained herein will be construed as restricting the right of either Party to make a timely report of such matter to any Regulating Groups or take other action that it deems to be appropriate or required by applicable law or regulation.

Baxter shall report to Cadence all adverse event reports on the Product as soon as possible but in no event later than two (2) business days of notification of the event to Baxter either directly or through Product Surveillance.

Cadence will be responsible for reporting all adverse events which relate to the Product as required by applicable legal requirements and the requirements of any Regulating Group.

EXHIBIT J
CONFIDENTIAL DISCLOSURE AGREEMENT

[***]

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EXHIBIT L
DEFINITIONS
(Section 2.0)

As used in this Agreement the following terms will have the following meanings:

The term “ADR” will have the meaning set forth in Section 16.0.

The term “Affiliate” will mean any corporation or business entity that controls, is controlled by, or is under common control with, Cadence or Baxter. A corporation or business entity will be deemed to control another corporation or business entity if it owns, directly or indirectly, fifty percent (50%) or more of the securities or other ownership interests representing the equity, the voting stock, or general partnership interest of such corporation or business entity.

The term “API” will mean the Compound supplied to Baxter by Cadence in accordance with the terms of this Agreement and the Specifications set forth in Exhibit A, as amended from time to time.

The term “API/Formulation Specifications” will have the meaning set forth in Section 14.2.1.

The term “API Manufacturing Process” will have the meaning set forth in Section 8.2.

The term “Background Intellectual Property Rights” will mean all patents, patent applications, copyrights, trade secrets, and other intellectual property rights owned by either Party or under which a Party otherwise has the right to grant licenses without accounting to any third party or to the other Party, where the inventions claimed, the works of authorship, or the know-how, trade secrets and the like, were not made in performance of activities pursuant to, or in anticipation of, this Agreement. For the avoidance of doubt, Baxter Background Intellectual Property rights do not include any such intellectual property rights developed by Baxter in its Grosotto facility and which is owned or licensed to the licensor of Cadence Licensed Intellectual Property.

The term “Baxter Capex” will have the meaning set forth in Section 4.1.5.

The term “Baxter Development Deliverables” will have the meaning set forth in Section 4.1.2.

The term “Baxter Patent Rights” will mean the rights granted by any governmental authority under a Patent that covers a method, apparatus, manufactured article, material or process necessary or useful for the manufacture of Product, which Patent is owned or Controlled by Baxter.

The term “Cadence Development Deliverables” will have the meaning set forth in Section 4.1.2.

The term “Cadence Licensed Intellectual Property” will mean those certain Patents and Patent Applications licensed and/or sublicensed to Cadence pursuant to the IV APAP Agreement and the Pharmatop License Agreement.

The term “Commercially Reasonable Efforts” will mean means the application by a Party, consistent with the exercise of prudent technical and business judgment, of diligent and sustained efforts and of material resources to fulfill the obligation in issue, consistent with the efforts a Party would devote to a pharmaceutical product of similar market and profit potential or strategic value at a similar stage in development or product life as the Product in issue, based on conditions then prevailing.

The term “competitor” will have the meaning set forth in Section 23.1.3.

The term “Compound” will mean N-**acetyl**-para-**aminophenol** (CAS Registry No. 103-90-2), also commonly referred to as acetaminophen and/or **paracetamol**.

The term “Confidentiality Agreement” will mean the two-way disclosure agreement, signed by the Parties, copies of which are attached to this Agreement as Exhibit J.

The term “Confidential Information” will have the meaning set forth in Section 13.0.

The term “Container” will mean the container portion of the Product as described in Exhibit A, as may be amended from time to time.

The term “Contract Year” will have the meaning set forth in Section 19.1.

The term “Control” will mean possession of the ability to grant the licenses or sublicenses as provided for in this Agreement without violating the terms of any agreement or arrangement with any third party.

The term “cGMP” or “Current Good Manufacturing Practices” will mean the good manufacturing practices required by the FDA and set forth in the FD&C Act or FDA regulations, policies, or guidelines (including ICH adopted guidelines) in effect at a particular time, for the manufacture and testing of pharmaceutical materials.

The term “Development Deliverables” will have the meaning set forth in Sections 4.1.2 and 4.1.3 and include the materials set forth on Exhibit B).

The term “Development Fees” will have the meaning set forth in Section 4.1.4.

The term “Development Plan” will mean the plan for development of the Product, as set forth in Exhibit B and described generally in Section 4.1.

The term “Development Program” will mean the development effort hereunder which

will enable Cadence to file an Regulatory Submissions with Regulating Groups in the Territory and which encompasses the tasks set forth on Exhibits B and C and the Development Deliverables set forth on Exhibit B.

The term “Drug Product Manufacturing Process” will have the meaning set forth in Section 10.3.

The term “Effective Date” will have the meaning set forth in the preamble to this Agreement.

The term “Estimated Requirements” will have the meaning set forth in Section 6.2.

The term “FDA” will mean the United States Food and Drug Administration and any successor agency and the corresponding regulatory authority of each jurisdiction in the Territory.

The term “FD&C Act” will mean the United States Federal Food, Drug and Cosmetic Act, as amended, or any corresponding Act of each jurisdiction in the Territory.

The term “Field” will mean the development for, registration and manufacture of, the Product.

The term “Force Majeure” will have the meaning set forth in Section 17.1.

The term “Formulation” will mean any and all premix, ready-to-use formulations containing the Compound.

The term “Formulation Specifications” will mean those specifications for the final release of the premix, ready-to-use solution that are developed and finalized by the Parties as part of the Development Program and which, together with the Container, are part of the Product Specifications.

The term “Information” will mean (i) techniques and data relating to the Field, including, but not limited to, ideas (including patentable inventions), inventions, practices, methods, knowledge, trade secrets, documents, apparatus, clinical and regulatory strategies, test data (including pharmacological, toxicological and clinical test data), analytical and quality control data, manufacturing, patent and legal data, market data, financial data within the Field and (ii) chemical formulations, compositions of matter, product samples and assays within the Field.

The term “Initial Term” will have the meaning set forth in Section 19.1.

The term “Integration Failure” will have the meaning set forth in Section 4.4.

The term “Inventions” will have the meaning set forth in Section 14.1.2.

The term “IV APAP Agreement” shall mean that certain IV APAP Agreement (US and Canada) dated February 21, 2006, by and between Bristol-Myers Squibb Company and Cadence,

as the same may be amended from time to time.

The term “Letter of Credit” will have the meaning set forth in Section 4.1.5.

The term “Letter of Intent” (LOI) will have the meaning set forth in Section 1.1.

The term “Manufacturing Fee” will mean the fee per unit paid by Cadence to Baxter for Product manufactured under this Agreement as described in Section 7.1 and Exhibit F.

The term “Matter” will have the meaning set forth in Section 15.3.

The term “Minimum Purchase Requirements” will have the meaning set forth in Section 6.1.2.

The term “NDA” will mean (i) a New Drug Application, as defined in the FD&C Act and applicable regulations promulgated thereunder, as amended from time to time, or any corresponding foreign application, registration, or certification of each jurisdiction in the Territory.

The term “Normal Manufacturing Process” shall mean the process beginning upon the mixing of the API by Baxter and ending when the finished Product is released into finished goods inventory at Baxter’s manufacturing facility.

The term “Original Product Data” will have the meaning set forth in Section 14.2.1.

The term “Party” or “Parties” will mean Cadence and Baxter individually, and collectively, as applicable.

The term “Patent” will mean (i) valid and enforceable letters patent including any extension, registration, continuation, reissue, reexamination or renewal thereof and (ii) to the extent valid and enforceable rights are granted by a governmental authority thereunder, a Patent Application.

The term “Patent Application” will mean an application for letters patent.

The term “Pharmatop License Agreement” shall mean that certain License Agreement dated December 23, 2002, between SCR Pharmatop and Bristol-Myers Squibb Company, as the same may be amended from time to time.

The term “Pre-Existing Specifications” will have the meaning set forth in Section 14.2.1.

The term “Product” will mean a premix, ready-to-use solution incorporating API that has (i) undergone the formulation process established under the Development Program and (ii) been packaged and terminally sterilized within the Container, all in accordance with the Product Specifications.

The term “Product Specifications” will mean the Formulation Specifications together with the Container description, which collectively describe the Product and are developed and finalized by the Parties as part of the Development Program as provided under Section 4.3.1 and thereafter as agreed by the Parties pursuant to the Quality Agreement. As of the Effective Date, provisional Product Specifications are set forth in Exhibit A.

The term “Quality Agreement” will mean the Quality Agreement, pursuant to Section 10.1, to be set forth in Exhibit G hereto.

The term “Regulating Groups “ will mean the FDA and its successors and similar governmental agencies outside the United States and in the Territory which are responsible for granting manufacturing, marketing, price and/or reimbursement price authorizations and includes applicable national, supra-national (e.g. the European Commission or the Council of the European Union), state or local Regulating Groups, department, bureau, commission, council or other governmental entity in the Territory that has jurisdiction over the API, Compound, Formulation or Product, whether the development, manufacture, handling, storage, transportation, destruction, or otherwise.

The term “Regulatory Strategy” will mean the principal regulatory considerations that are associated with Product development during the Development Program as set forth in Exhibit C and described generally in Section 4.2.

The term “Regulatory Submissions” will mean those applications and filings identified in the Regulatory Strategy and required by FDA regulations, as amended from time-to-time, and the equivalent applications and filing for each country or super-national jurisdiction in the Territory, including but not limited to, the Product NDA or Investigational New Drug Application (INDA).

The term “Reports” will have the meaning set forth in Section 14.2.1.

The term “Requirements” will have the meaning set forth in Section 6.1.

The term “Team Leaders” will have the meaning set forth in Section 3.1.

The term “Technical Failure” will have the meaning set forth in Section 4.4.

The term “Term of the Agreement” will have the meaning set forth in Section 19.1.

The term “Territory” will mean the United States and any additional countries added by written agreement of the Parties.

The term “Third Party” will mean any natural person, corporation, general partnership, limited partnership, joint venture, proprietorship, or other business organization who is not a Party or an Affiliate of a Party to this Agreement.