UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported): January 28, 2011

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)

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))			

Item 1.01. Entry into a Material Definitive Agreement.

On January 28, 2011, Cadence Pharmaceuticals, Inc. (the "Company") entered into an Amended and Restated Development and Supply Agreement (the "Agreement") with Baxter Healthcare Corporation ("Baxter"), which amended and restated the original agreement entered into between the parties on July 18, 2007, as amended, for the manufacture of OFIRMEVTM (acetaminophen) injection for commercial distribution by the Company in the United States.

Pursuant to the terms of the Agreement, the Company will pay Baxter a per unit purchase price based on the amount of finished OFIRMEV drug product produced, which price will be increased annually, and may be adjusted to reflect an increase or decrease, as the case may be, in the cost of material required to manufacture OFIRMEV, subject to specified limitations. The Company is obligated to purchase a minimum number of units of OFIRMEV each year or pay Baxter an amount equal to the purchase price multiplied by the shortfall in units. In addition, Baxter will be the Company's primary supplier of OFIRMEV up to a specified number of units in each year, subject to Baxter's ability to timely supply the specified volumes required by the Company. However, if Baxter fails or declines to supply a sufficient quantity of OFIRMEV in accordance with the Company's purchase orders during a specified period of time, then the Company may purchase that OFIRMEV from third party suppliers and such quantity will be deducted from the quantity of OFIRMEV that the Company otherwise would have been required to purchase from Baxter. 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.

Under the Agreement, the Company and Baxter agreed to complete a capacity increase development plan for the expansion of the manufacturing capacity for OFIRMEV at Baxter's facilities. All capital equipment and facility improvements included in the plan will be funded by the Company. The Company will not be able to reasonably estimate the cost of expansion until the capacity increase development plan has been completed.

The initial term of the Agreement will terminate on November 1, 2015, and will automatically renew for successive one-year periods thereafter, unless either party provides at least two years prior written notice of termination to the other party. In addition, either party may terminate the Agreement (1) within 90 days, after written notice in the event of a material uncured breach of the Agreement by the other party or (2) immediately, upon the filing of a petition of bankruptcy by the other party. The Company 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 the Company to a competitor of Baxter. Baxter has agreed that, for the initial term and any renewals or extensions 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.

If the Agreement is terminated, except as a result of a material uncured breach or bankruptcy by Baxter, the Company will reimburse Baxter for all materials ordered prior to the termination of the agreement that are not cancelable at no cost to Baxter. 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 the Company, at the price in effect at the time the purchase order was placed. The Company is also obligated to reimburse Baxter for reasonable costs incurred in returning all Company-owned equipment and for restoring Baxter's manufacturing facility to its condition prior to the installation of OFIRMEV-related improvements, other than restoration costs for changes that Baxter reasonably agrees are usable by Baxter at the time of removal of the Company-owned equipment. The Company is not able to reasonably estimate the cost and the timing of these expenses at this time and therefore cannot reasonably estimate the fair value of the retirement obligation.

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 is 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.

Exhibit	
Number	Description of Exhibit
10.1†	Amended and Restated Development and Supply Agreement, dated January 28, 2011, 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: February 2, 2011

EXHIBIT INDEX

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[†] 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

AMENDED & RESTATED DEVELOPMENT AND SUPPLY AGREEMENT

By and Between

CADENCE PHARMACEUTICALS, INC.

and

BAXTER HEALTHCARE CORPORATION

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CONFIDENTIAL

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AMENDED AND RESTATED DEVELOPMENT AND SUPPLY AGREEMENT

This **AMENDED AND RESTATED DEVELOPMENT AND SUPPLY AGREEMENT**, (this "**Agreement**") is effective as of January 28, 2011 (the "**Effective Date**") by and 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 of, and manufacturing process for, the Compound.

Baxter manufactures and markets sterile products in glass containers for parenteral administration of pharmaceutical preparations.

Cadence and Baxter entered into a Letter of Intent dated November 27, 2006, as amended (collectively, the "LOI"), and executed a Development and Supply Agreement dated July 18, 2007, as amended on October 11, 2007, March 1, 2009, October 15, 2009, and June 7, 2010 (collectively, the "Original Agreement"), with respect to the provision of certain development and commercial supply services by Baxter.

The Parties now wish to modify the terms of the Original Agreement to confirm the terms and conditions under which Baxter will manufacture the Product for commercial distribution, and establish the terms and conditions under which the commercial manufacturing capacity for the Product at the Facility will be expanded. Upon the Effective Date, the LOI and the Original Agreement shall be superseded in their 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 I.

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 Product Manager.** 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 "**Product Manager**"), who will be responsible for obtaining cooperation and input from other individuals within such Product Manager's organization whose expertise and ability may be required from time to time to ensure the success of the collaboration between the Parties under this Agreement.
- **3.2 Steering Committee.** The Parties shall establish a steering committee, consisting of at least one general business executive and one senior technical executive from both Parties ("Steering Committee"). The Steering Committee will meet at least quarterly, through face-to-face meetings at a mutually convenient location or via telephone conferences and/or videoconferences, at times to be mutually agreed. The Steering Committee will discuss and resolve any overarching questions or issues and discuss future plans and the relationship between the Parties. The Steering Committee shall not have the authority to modify, supplement, amend or terminate this Agreement. If the Steering Committee is unable to resolve any such differences, the matter(s) shall be escalated to the Chief Commercial Officer for Cadence and the VP, Sales for Baxter BioPharma Solutions for Baxter (the "Senior Executives"). If the Senior Executives are unable to resolve any such differences, the matter shall be handled pursuant to Article 16.0 of this Agreement.
- **3.3 Cadence Product Manager in Facility**. Baxter agrees to provide office accommodations in its Facility, on the conditions set forth below, to the Cadence Product Manager or his/her designee, specializing in manufacturing processes. Baxter may, in its sole discretion, at any time, revoke its offer to provide office space in its Facility for a specific individual serving as Product Manager or his/her designee, or for the Cadence Product Manager position, following sixty (60) days' prior written notice to Cadence.
- 3.3.1 The Cadence Product Manager (and any designee) shall on an annual basis agree to (i) undergo training on Baxter's security, safety, and emergency procedures at the Facility, (e.g. site evacuation procedures) within a timeframe agreed to between Cadence and Baxter's Facility Management team, (ii) undergo training on GMP requirements and specific site interpretations and application, and (iii) abide by all training requirements. Training requirements specified above will be documented by Baxter in a written communication, with a training plan and timeframe for completion agreed to by the Parties. The completion of the training will also be documented in written communication to Cadence.
- **3.3.2** In order to protect the confidentiality of Baxter and any third parties, Baxter Facility personnel may restrict the Cadence Product Manager position's access to certain conference rooms or other areas at the Facility. In general, the Cadence Product Manager position's access shall be limited to those areas relevant to the manufacture of the Product. In the event Baxter designates certain areas as restricted to the Cadence Product Manager position, the Cadence Product Manager and any designee agree not to enter such areas.

4.0 DEVELOPMENT PLANS

4.1 Development Plans

- **4.1.1 NDA Development Plan.** The Parties acknowledge the completion of the NDA Development Plan concurrent with the approval of an NDA for the Product by the FDA on November 2, 2010.
- **4.1.2** Capacity Increase Development Plan. Within sixty (60) days after the Effective Date, or such longer time period as may be mutually agreed upon by the Parties, the Parties will mutually agree upon a development plan (using the development plan template attached as Exhibit H or a substantially similar form) for the expansion of the manufacturing capacity for the Product at the Facility (the "Capacity Increase Development Plan"). The Capacity Increase Development Plan will identify in detail the scope of the activities to be performed and the fees associated with such activities. All capital equipment and Facility improvements included therein will be funded by Cadence. The Capacity Increase Development Plan will also include provisions detailing the process by which Baxter will agree to accept the completed, validated second manufacturing line for the Product to be installed at the Facility. The Parties agree to work together to resolve in good faith any outstanding disagreements with respect to the Capacity Increase Development Plan and, following approval by both Parties, the Capacity Increase Development Plan shall be incorporated by reference as part of this Agreement. Each Party shall use Commercially Reasonable Efforts to timely accomplish the tasks that it is assigned under the Capacity Increase Development Plan.
- **4.1.3 Additional Development Plans.** The Parties may, from time to time, mutually agree upon one or more development plans (using the development plan template attached as Exhibit H or a substantially similar form), which will identify in detail the scope of the activities to be performed and the fees associated with the activities (each, a "**Development Plan**"). Cadence will initiate each new Development Plan and send the draft Development Plan to Baxter for review and comment. The Parties agree to work together to resolve in good faith any outstanding disagreements with respect to each Development Plan. Unless otherwise agreed in writing by a duly authorized representative of each Party, in no event shall Baxter purchase any Materials or equipment or schedule or commence any work, and Baxter shall not be obligated to do so, until a Development Plan has been fully executed by both Parties. Each executed Development Plan shall be incorporated by reference as part of this Agreement. Each Party shall use Commercially Reasonable Efforts to timely accomplish the tasks that it is assigned under each Development Plan.

4.2 Provisions Generally Applicable to Development Plans. The activities and key milestones to occur with respect to each Development Plan may include, but are not limited to, the following activities or topics: (i) technical feasibility assessment, (ii) formulation and analytical development, (iii) Facility improvements, (iv) equipment and Material purchases, (v) clinical scale production, (vi) stability studies and Product batch production to support Regulatory Submissions, (vii) Regulatory Submissions, (viii) Regulating Groups' review and approval, and (ix) Product launch readiness activities and other pre-commercial activities. If different from the Product Specifications, specifications applicable to Product to be manufactured under each Development Plan will be set forth in each such plan, subject to refinement from time to time based upon the results of the Development Plan, the results of ongoing activities under other Development Plans, and requirements of Regulating Groups. While Product and Formulation specifications, and any changes thereto, must be agreed to in writing by both Parties, Cadence will be responsible for and must provide final approval of all Product specifications and any Formulation specifications included in Development Plans, and all changes thereto prior to implementation.

During the Term of the Agreement, Cadence will be responsible for performing certain Cadence activities as set forth in each Development Plan, including but not limited to, the following: (i) providing technical information about the API and the manufacturing process for Product, (ii) unless otherwise agreed in writing by a duly authorized representative of each Party, timely providing the API and applicable reference standards required for implementation of the activities described in the Development Plans, (iii) unless otherwise agreed between the Parties, compliance with Regulatory Submission reporting requirements regarding manufacture and control of the API, (iv) timely review, drafting and filing of all necessary submissions with Regulating Groups, and (v) payment of development fees and other fees and expenses as set forth in Section 4.2.3.

In general, during the Term of the Agreement, Baxter will be responsible for performing certain activities as set forth in each Development Plan, including but not limited to, the following: (a) conducting development studies identified as a Baxter Development Deliverable in each Development Plan, (b) maintaining inventories of excipients, applicable reference standards and other components and Materials required as agreed in each Development Plan for timely implementation of the activities described therein, (c) manufacturing Product for Regulatory Submissions and as otherwise provided in each Development Plan and pursuant to the applicable Regulatory Strategy, (d) preparing those portions of necessary submissions with Regulating Groups consistent with Baxter's obligations under the applicable Regulatory Strategy, and (e) supporting Cadence in its efforts to obtain and maintain approval of the Regulating Groups to sell the Product in the Territory.

4.2.1 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 Plans ("Baxter Development Deliverables") which will include such interim progress reports and final reports as may be 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 Plans ("Cadence Development Deliverables").

4.2.2 Additional Development Deliverables. If the Baxter Development Deliverables or the Cadence Development Deliverables set forth in a Development Plan 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 Article 5.0 or to complete the FDA's Annual Report and similar reports required by other Regulating Groups, or to obtain Patent protection in accordance with Article 14.0, the Parties will in good faith negotiate and execute an Amended and Restated Development Plan 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. Baxter will not be required to perform, nor be entitled to reimbursement for, any work beyond that described in a Development Plan(s) unless and until the Parties reach written agreement on the scope of any additional work and the related additional expenses (coordinated through the Product Managers under Section 3.1), and an Amended and Restated Development Plan has been executed by both Parties.

4.2.3 Payment of Development Fees and Costs. Development fees payable by Cadence to Baxter for the Baxter Development Deliverables as set forth in each Development Plan, costs for Material and equipment purchases and Facility improvements, and any other fees and expenses agreed upon by the Parties as set forth in a Development Plan, 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. Baxter agrees that all such invoices will be provided to Cadence on a timely basis, which shall in no event be later than sixty (60) days following the date on which Baxter incurs any such fees or expenses, and shall contain a reference to the Development Plan to which the invoice relates. 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.

4.3 Regulatory Strategies. Cadence shall be solely responsible any regulatory strategies and considerations associated with each Development Plan. Any development or regulatory-related activities required to be undertaken by Baxter in support of Cadence's regulatory strategies associated shall be set forth in each Development Plan. Cadence may revise its regulatory strategies for any Development Plan, subject to prior written agreement between the Parties in the event that any such change is reasonably anticipated to impact the cost and timetable of the development or regulatory-related activities specified in the Development Plan. Cadence will discuss with Baxter any elements of its regulatory strategies which may reasonably be expected to have an impact on Baxter's obligations under this Agreement.

- **4.4 Stability Studies**. Baxter shall perform at no additional cost to Cadence on an on-going basis one (1) annual stability study required by the Specifications, Applicable Laws, and the NDA for the Product, and the Quality Agreement in connection with the manufacture of the Product.
- **4.5 Technical Issues.** The Parties acknowledge and agree that, as a result of the approval of an NDA for the Product by the FDA, the terms "Technical Failure" and "Integration Failure" (as defined in the Original Agreement) are no longer applicable to this Agreement.

5.0 PRODUCT REGISTRATIONS AND USER FEES

5.1 Product Registration Application Ownership. Cadence will be the sole 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 and for completing the FDA Annual Report and similar reports required by other Regulating Groups, with support from Baxter in providing any information required from Baxter in order to complete such reports. Communications to and from the Regulating Groups that involve the NDA or any other Regulatory Submissions are subject to the provisions of Section 5.3.

5.2 Product Registration and User Fees.

- **5.2.1 Right of Reference Drug Master File.** Baxter acknowledges that it holds DMF [***]. Baxter will provide a letter of authorization for DMF [***] to Cadence to support the container closure system and parametric release of the Product in lieu of end-product testing. The right of reference does not include Cadence access to DMF [***]. In the event of a critical regulatory issue with the Product, such as a product recall, Baxter will provide appropriate data, technical reports, and other information to Cadence regarding the issue, including information that may reside in DMF [***]; provided, however, that Baxter reserves the right to redact to protect its Confidential Information or the confidential information of third parties.
- 5.2.2 **Additional Filing Data**. During the Term of the Agreement, Baxter will, following prior written review and approval of Cadence, provide the Regulating Groups such additional data and information related to the Product as 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 Regulating Groups that such information is confidential and to advise the Regulating Groups that Cadence will be entitled to reference such information on a confidential basis during the Term of the Agreement.
- *** 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.

5.3 Communications to/from Regulating Groups.

5.3.1 Communications from Regulating Groups. Each Party will promptly notify the other Party of any communication from Regulating Groups related to the Product or the activities of the Parties contemplated under this Agreement (collectively, "Communication(s)"). Each Party reserves the right to redact its Confidential Information or confidential third party information.

5.3.2 Communications to Regulating Groups. In the event that a response to a Regulating Group is required in connection with any Communication, the Parties will use reasonable efforts to agree on which individuals need to collaborate on such responses. Cadence will have primary responsibility to respond to all Communications from Regulating Groups in connection with any Cadence Regulatory Submission regarding the Product (including the vial, stopper, cap and all labeling for the Product), the API or the Formulation, and any non-Product specific information related to Cadence, and Baxter will have primary responsibility to respond to all Communications from Regulating Groups in connection with DMF [***], the Facility, container closure integrity and sterility assurance for the Product, and any non-Product specific information related to Baxter. Each Party will collaborate in good faith with the other Party in preparing such responses, and Baxter will provide Cadence with information that the Parties reasonably agree is required to develop a requested response for questions directed to any Cadence Regulatory Submission or other Communication. In the event that Baxter and Cadence are unable to agree on the final content of any such response, then Cadence's position will prevail as it pertains to all Communications sent to Regulating Groups relating to the API, Formulation, or the Product (including the vial, stopper, cap and all labeling for the Product), and Baxter's position will prevail as it pertains to DMF [***], the Facility, container closure integrity and sterility assurance for the Product. If requested, Baxter will allow an agreed upon third party to review redacted portions of DMF [***] where information is required to be shared with Regulating Groups pertaining to the Product; provided, however that Baxter has the ability to set reasonable conditions upon the review parameters and to protect its Confidential Information and the confidential information of third parties.

5.4 User Fees. Cadence will pay all user and/or filing fees charged to Cadence by Regulating Groups that 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

6.1 Product Standards, Specifications and Materials.

6.1.1 Standards. Baxter shall manufacture, test, package, store, label, release and deliver the Product in accordance with the Product Specifications, Applicable Laws, the NDA for the Product, and the Quality Agreement. Baxter shall also maintain the Facility in compliance with all Applicable Laws and the Quality Agreement, and shall be responsible for all costs and expenses related to the maintenance of the Facility in compliance therewith.

*** 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.

- **6.1.2 Product Specifications**. Exhibit A includes Product Specifications in effect as of the Effective Date. The Quality Agreement shall govern the procedures for making changes to Product Specifications for commercial Product. Cadence will be responsible for and must provide final approval of Product Specifications and all changes thereto prior to implementation.
- **6.1.3 Materials**. Baxter shall procure the Materials at such times, and in such amounts consistent with the amounts forecasted per Section 6.3 and as shall be necessary in order for Baxter to timely produce and deliver the Product as requested by Cadence in accordance with this Agreement. Both Parties agree to work together to reduce lead time for orders and deliveries of the Materials. Baxter shall obtain the Materials only from suppliers listed in the NDA for the Product, where applicable, and shall perform all testing of Materials required by the Product NDA for the Product or Quality Agreement. Audit and qualification of third party suppliers of raw Materials shall be handled in accordance with the Quality Agreement.
- **6.1.4 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.
- **6.2 Supply and Purchase Obligations.** Baxter will be the supplier for, and Cadence will purchase from Baxter, [***] units of the Requirements during each Contract Year during the Initial Term. Additionally, Baxter will be the supplier for, and Cadence will purchase from Baxter, [***] units of the Requirements during each Contract Year, if any, following the Initial Term.
- **6.2.1** Notwithstanding Cadence's obligation to purchase [***] units of the Requirements from Baxter during each Contract Year during the Initial Term, or [***] units of the Requirements during each Contract Year following the Initial Term, as applicable:
- **6.2.1.1** If Baxter has failed to provide at least [***] percent ([***]%) of the quantity of Product in accordance with each Firm Purchase Order (including, without limitation, within the delivery time frames set forth in such Firm Purchase Orders) during any [***] period, Cadence may purchase from other suppliers the Product that Baxter failed to deliver and such quantity will be deducted from the [***] units, or from the [***] units, as applicable, of the Requirements that Cadence is obligated to purchase for that Contract Year under Section 6.2.1; and
- *** 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.

6.2.1.2 If, despite the collaboration of the Parties under Section 6.3, Baxter has not accepted (pursuant to Section 6.4.2, below) and committed to timely provide to Cadence at least [***] ([***]%) of the quantity of Product included in each purchase order submitted by Cadence to Baxter in accordance with Section 6.4.1 for any [***] period, Cadence may purchase from other suppliers the Product that Baxter has not committed to timely supply, and such quantity will be deducted from the [***] units, or from the [***] units, as applicable, of the Requirements that Cadence is obligated to purchase for that Contract Year under Section 6.2.1.

6.2.2 Minimum Purchase Requirement. During the Initial Term, Cadence shall purchase from Baxter, at a minimum, the number of units of Product for each Contract Year as set forth below ("Minimum Purchase Requirement"):

Contract Year Commencing:	Units (Million)
Nov. 1, 2010	[***]
Nov. 1, 2011	[***]
Nov. 1, 2012	[***]
Nov. 1, 2013	[***]
Nov. 1, 2014	[***]
Each additional year (if any)	[***]

These units will be ordered in the Minimum Batch Size. 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 Manufacturing Fee 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.

6.3 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 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 and Baxter will collaborate in good faith, using the Estimated Requirements, to plan for production such that substantial increases or decreases in production may, generally, be spread gradually over each Contract Year; provided, however, the Cadence's actual market demand for the Product shall in all cases take precedence over any such scheduling agreements. 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 Section 6.4.3.

*** 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.

6.4 Purchase Orders; Firm Purchase Orders.

- **6.4.1 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 the Product, ordered pursuant to the process set forth in this Section 6.4, including, but not limited to volume variations and subject to the restrictions set forth herein. Cadence will place purchase orders for the portion of its Requirements for Product required during each calendar quarter at least ninety (90) calendar days prior to the beginning of each such calendar quarter. Each purchase order will specify the individual Product order quantities by month for the quarter. Purchase orders will be placed in increments of no less than the Minimum Batch Size. Baxter will confirm its ability, or inability, to provide Product in the month for which Cadence has requested delivery as further set forth in Section 6.4.2. Subject to the provisions of Section 6.2, all such purchase orders will not be less than [***] percent ([***]%) nor more than [***] percent ([***]%) of Cadence's most recently updated Estimated Requirements for Product for such calendar quarter.
- **6.4.2 Acceptance.** Within ten (10) days, Baxter will accept or reject each purchase order received from Cadence by providing a written notice confirming its ability to manufacture the quantity of the Product specified therein, and including the associated price and month within which the manufacture of the Product will occur. For the purposes of this Agreement each purchase order accepted by Baxter and each purchase order which is neither accepted or rejected by Baxter within ten (10) days of Baxter's receipt of same, shall be a "**Firm Purchase Order**." Baxter shall supply Product pursuant to each Firm Purchase Order, *provided*, that each Firm Purchase Order shall be deemed to have been fully satisfied if the quantity of each of the Product supplied thereunder is not more than [***] percent ([***]%) and not less than [***] percent ([***]%) of the quantity of Product ordered therein.

6.4.3 Cancellations and Rescheduling. Notwithstanding the foregoing Section 6.4.1:

- **6.4.3.1** 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;
- **6.4.3.2** Cadence may cancel a Firm Purchase Order, subject to the payment of a cancellation fee of [***] percent ([***]%) of the amount of any such cancelled Firm Purchase Order penalty if Cadence notifies Baxter of such cancellation within [***] days of the date on which Baxter had scheduled the manufacture such Product; and
- **6.4.3.3** Cadence may reschedule a Firm Purchase Order, subject to the payment of a rescheduling fee of [***]% of the amount of any such rescheduled Firm Purchase Order if Cadence notifies Baxter of such rescheduling within [***] days of the date on which Baxter had scheduled the manufacture such Product.
- *** 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.

- **6.4.4 Forms.** 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.
- **6.5 Delivery; Shipment.** All Product supplied under this Agreement will be delivered FCA Baxter's distribution site in Memphis, Tennessee. 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 on or before the delivery date. Baxter shall be responsible for loading the Products to be shipped with the designated carrier.
- **6.6 Title/Risk of Loss**. Title to and risk of loss with respect to the Product shall pass from Baxter to Cadence when picked up by the carrier at the Facility. All Products delivered to Cadence shall be free and clear of any liens and encumbrances.
- **6.7 Exporter of record.** 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 C, 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 in the NDA for the Product and Product Specifications, as may be amended from time to time. The Quality Agreement shall ultimately govern release of Product for delivery to Cadence.

7.2 Adjustments to Manufacturing Fee.

- **7.2.1** Effective upon the commencement of each Contract Year beginning on November 1, 2011, Baxter will increase the Manufacturing Fee by an amount equal to \$[***] per unit or [***], whichever is greater. Baxter will provide Cadence with written notice ninety (90) days prior to the effective date of any such increase in the Manufacturing Fee, which notice shall set forth the amount and basis for such increase.
- **7.2.2** Effective upon the commencement of each Contract Year beginning on November 1, 2011, the Manufacturing Fee may be adjusted by Baxter to reflect an increase or decrease, as the case may be, in the cost of Material required to manufacture the Product,
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provided, however, that any such increase or decrease in Material cost is greater than [***] percent ([***]%) of the average cost to purchase such Material during the previous Contract Year. Baxter will provide Cadence with written notice ninety (90) days prior to the effective date of any such increase or decrease in the Manufacturing Fee, which notice shall set forth the amount and basis for such increase or decrease.

- **7.2.3** Additionally, the Manufacturing Fee will be reduced, on a "pass-through" basis, to reflect the decrease, if any, in the cost of any Material that results from any cost concession, volume purchase commitment, or other negotiation with the supplier of such Material by Cadence or on Cadence's behalf. All such cost decreases will be applied to the Manufacturing Fee at the time that the Material to which the cost decrease applies is first used to manufacture the Product.
- 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 Exhibits hereto, Applicable Laws and the Quality Agreement. 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, Applicable Laws, Quality Agreement, and other Exhibits. By way of example only, additional work might be required for Product or process changes requested by the Regulating Groups, API source changes or API 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 shall be set forth in a Development Plan.
- **7.4 Improvement Initiatives.** From time to time either Baxter or Cadence individually or Baxter and Cadence working collaboratively may propose changes to the Normal Manufacturing Process that result in improvements to efficiency, throughput, Product quality, Materials cost or other benefits to either or both of the Parties ("**Improvements**").
- 7.4.1 Cadence may at any time request Improvements, *provided*, that Cadence and Baxter agree to a Development Plan to the Development Agreement that details the project to implement the Improvement, and *provided*, that the Improvement does not adversely affect Facility operations or lead to major process changes outside of the Cadence Owned Equipment. Any costs and expenses of such Improvements, as well as any cost savings that result from the Improvement, shall be allocated as mutually agreed in writing between the Parties in the Development Plan. To be clear, the percentage split between the Parties of the actual savings attributed to Improvements requiring capital investment to the Facility shall be agreed upon at the time that such capital investments are proposed. Ownership of the capital equipment and capital improvements resultant from such capital investment shall also be agreed upon at the time that the capital improvements are proposed.
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- 7.4.2 Baxter may implement Improvements of its own and sole initiative, *provided*, that any such Improvements initiated by Baxter shall only be made in accordance with Section 10.8, and *provided*, that any such Improvement shall be made at Baxter's sole cost and expense. To be clear, any costs savings as may be realized by Improvement of the sole initiative and expense of Baxter shall accrue exclusively to Baxter.
- 7.5 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 9.4), 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. Invoices not timely paid will be subject to a late payment charge of [***] percent ([***]%) per month, or the highest amount permitted by law, if lower. Notwithstanding the foregoing, should Cadence give Baxter a Deficiency Notice pursuant to Section 10.2, Cadence's obligation to pay under this Section 7.5 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 the Facility. 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 B, 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. Cadence is responsible for the quality and control of any API provided by Cadence and the API Specifications. Cadence is also responsible for the quality and control of any other components or raw Materials provided by Cadence to Baxter, including without limitation, the suppliers of such components and raw Materials and the related specifications.
- **8.2** Change of API Source or API Manufacturing Process. Cadence agrees to provide written notice to Baxter of any proposed change to the API source, or any change in the manufacturing process for the API as soon as possible (e.g., upon receipt of notice from their supplier.) Following such written notice to Baxter, the Parties will work together to promptly agree upon a Development Plan with respect to any work reasonably required of Baxter to support Cadence's filings with the Regulating Groups to obtain approval for such change. Under
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any such Development Plan, Cadence will reimburse Baxter for all reasonable costs incurred by Baxter directly related to work performed by Baxter 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. Except pursuant to a Development Plan agreed upon by the Parties, Baxter shall not be required to manufacture the Product using API from a new source or API that has been manufactured using an API manufacturing process that has been modified such that approval by the Regulating Groups is required in order to market, sell and distribute the Product in the Territory, unless and until such change is approved by applicable Regulating Groups.

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

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.

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.

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.

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 [***] percent ([***]%) 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 each Contract Year. Baxter will be responsible for calculating actual yield loss percentage as per the methodology set forth in Exhibit D, which is
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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 AND FACILITIES

- **9.1 Compliance with Applicable Laws**. Baxter shall at all times during the Term of the Agreement maintain the Facility and all other Baxter locations that provide services under this Agreement in compliance with Applicable Laws. Baxter shall be responsible for all costs and expenses required to maintain the Facility and such other Baxter locations in compliance with Applicable Laws, *provided*, *however*, that if Facility, equipment, process, or system changes are necessary in order to maintain compliance with Applicable Laws, and if the changes would not be necessary but for Baxter's manufacturing activities for the Product, then, upon Cadence's agreement with the necessity for such changes and the reasonableness of the anticipated costs and expenses, Cadence shall bear such costs and expenses in accordance with this Agreement. Baxter shall notify Cadence promptly if it reasonably determines that any such changes are required and will include in any such notification the anticipated costs and expenses associated with such changes.
- **9.2 Baxter Owned Equipment and Risk of Loss.** All equipment supplied, owned or purchased by Baxter and paid for by Cadence as of the Effective Date is set forth in Exhibit E ("Baxter Owned Equipment"). The 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, 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.
- **9.3 Cadence Owned Equipment and Risk of Loss**. All equipment supplied, owned or purchased by Cadence as of the Effective Date is set forth in Exhibit F ("Cadence Owned Equipment"). All 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.

9.4 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.

9.5 Performance Expectations for Cadence Owned Equipment. Within ninety (90) days after the Effective Date, Cadence and Baxter will mutually agree in writing on operating specifications for the Specified Equipment. Baxter will not be deemed in breach of its obligation to deliver Product ordered under a Firm Purchase Order to the extent such non-delivery or delayed delivery is caused by the failure of the Specified Equipment to perform in accordance with such operating specifications for the Specified Equipment (an "Equipment Failure Event"); provided, that such failure is not due to Baxter's negligence or willful misconduct, or any other cause within Baxter's reasonable control; and provided, that Baxter (i) promptly notifies Cadence of the Equipment Failure Event as provided in Section 17.2, (ii) uses reasonable diligence and efforts to remedy the situation if reasonably capable of being remedied by Baxter, (iii) continues performance of its obligations to the extent the Equipment Failure Event permits, and (iv) resumes performance of its obligations delayed by the Equipment Failure Event as soon as possible.

10.0 QUALITY MANAGEMENT

10.1 Quality Agreement. The terms contained in the Quality Agreement are intended to complement the terms of this Agreement, and they shall be interpreted as complementary to the extent possible. In the event of a conflict between the terms of the Quality Agreement and the terms of this Agreement, the terms of this Agreement shall control with respect to business, financial and legal matters, and the terms of the Quality Agreement shall control with respect to quality control and quality assurance matters related to the Product (including, without limitation, manufacturing, testing, storage, release, change management and validation activities); *provided*, *however*, that the inclusion of a particular term or level of detail in the Quality Agreement where such term or level of detail is absent from this Agreement shall not be deemed to constitute a conflict between the two agreements. Only where competing terms in the two agreements conflict in terms of the principal focus of an express prescription or prohibition in the agreements shall a conflict between the two agreements be deemed to exist.

10.2 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, at the expense of Baxter, Products that

deviate from the Product Specifications or Applicable Laws. Cadence or its designated agent shall review the batch documentation as set forth in the Quality Agreement and shall give Baxter written notice (a "Deficiency Notice") of all claims for Products that deviate from the Product Specifications or Applicable Laws within [***] ([***]) days after Cadence's receipt of the final, Baxter-approved Batch Disposition Certificate for the batch of Product in question (or, in the case of any defects not reasonably susceptible to discovery upon receipt of such final, Baxter-approved Batch Disposition Certificate, within [***] ([***]) 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 [***] ([***])-day period, then the Product shall be deemed to have been accepted by Cadence on the [***] day after Cadence's receipt of the final, Baxter-approved Batch Disposition Certificate or discovery of the deficiency, 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 [***]-day period. Baxter shall use Commercially Reasonable Efforts to replace the non-compliant Product promptly. Any API consumed in producing non-compliant Product will be included in the annual yield loss calculation as set forth in Section 8.4.

- 10.2.1 If Baxter and Cadence do not agree as to whether or not the Product is non-compliant with the Product Specifications, then the Parties shall agree upon a specialized laboratory of recognized reputation for the purpose of determining the results. Any determination by such laboratory shall be final and binding upon the Parties hereto.
- 10.2.21 If Baxter and Cadence do not agree as to whether or not the Product is non-compliant with Applicable Laws, then the dispute shall be resolved in accordance with Section 16.0 of this Agreement ("Alternative Dispute Resolution"), *provided*, *however*, that if the Parties agree that such dispute would more appropriately be resolved in accordance with the procedure set forth in Section 10.2.1, then that procedure will be used, instead.
- 10.2.3 If the Product is confirmed to be non-compliant with the Product Specifications, in accordance with Section 10.2.1, or Applicable Laws, in accordance with Section 10.2.2, as applicable, Baxter shall pay all costs associated with such analysis, and Cadence shall not be required to pay the Manufacturing Fee for such Product. If Product is confirmed to be compliant, Cadence shall pay all costs associated with such analysis, in addition to paying the Manufacturing Fee for such Product.
- 10.3 Product Recalls. Cadence shall determine if a Product recall or marketing withdrawal is required, and shall be responsible for the conduct of any such recall or marketing withdrawal; provided, however, that Baxter shall reasonably cooperate with any such action. If a Product recall results from the gross negligence or intentional misconduct of Baxter, Baxter will promptly replace the Product and reimburse Cadence for the 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
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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.

- 10.4 Product Complaints. Product Complaints shall be handled in accordance with the Quality Agreement. In general, Baxter shall promptly notify Cadence of any and all complaints of which Baxter becomes aware relating to any Product, and shall forward to Cadence's designated quality representative or such other individual as Cadence shall designate a copy of any such written complaint received by Baxter. Cadence shall promptly inform Baxter of any and all complaints that Cadence receives which implicate Baxter's manufacturing or other processes at the Facility. Notification shall be given by telephone, with a facsimile confirmation immediately following.
- 10.5 Adverse Events ("AE"). Adverse Events shall be handled in accordance with the Quality Agreement. With respect to any Product, Baxter shall notify Cadence in accordance with the timeline set forth in the Quality Agreement following Baxter's receipt of written information of an Adverse Event. To the extent an Adverse Event of which Cadence becomes aware implicates Baxter's manufacturing or other processes at the Facility, Cadence shall inform Baxter in accordance with the timeline set forth in the Quality Agreement of such Adverse Event and shall disclose to Baxter any information it has regarding that Adverse Event.
 - 10.6 Retained Samples. Baxter shall retain samples from each batch of Products in accordance with the Quality Agreement.
- 10.7 Changes to Product Specifications. The Product Specifications may not be amended, changed or supplemented by Baxter without the prior written consent of Cadence. 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 7.4. Baxter will provide Cadence with all information needed to amend the NDA for the Product and other Regulatory Submissions as a result of any approved Product Specification change. Baxter will continue to supply Cadence with Product approved under Cadence's NDA for the Product and other Regulatory Submissions until such time as the changed Product Specifications are permitted by each of the applicable Regulating Groups, except as the Parties otherwise agree by separate written agreement.

10.8 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 NDA for the Product and other Regulatory Submissions as a result of any approved Drug Product Manufacturing Process change. Baxter will continue to supply Cadence with Product approved under Cadence's NDA for the Product and other Regulatory Submissions until such time as the Product manufactured under the changed process is permitted by each of the applicable Regulating Groups, except as the Parties otherwise agree by separate written agreement. Notwithstanding the foregoing, in the event any changes to the Drug Product Manufacturing Process 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 other changes to the Drug Product Manufacturing Process requested by Cadence shall be the responsibility of C

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. 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; (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; 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.

12.2.2 Replacement.

12.2.2.1 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, Cadence's sole obligation and Baxter's exclusive remedy will be limited to replacement of the API (subject to the provisions of this Section).

12.2.2.2 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, then Cadence's obligation will also include payment to Baxter of the Manufacturing Fee per unit of Product required to be replaced using non-defective API.

12.2.2.3 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 the 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; (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; 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. 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.
- **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 Laws; (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.
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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 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. Any API consumed in producing defective Product will be included in the annual yield loss calculation as set forth in Section 8.4. 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 Article 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 Preexisting Confidentiality Agreement.** The Parties have previously signed a Confidential Disclosure Agreement effective April 6, 2006, a copy of which is attached to this Agreement as Exhibit *G*, 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 Confidential Disclosure Agreement.
- **13.3 Exceptions.** In addition to the exceptions set forth in the Confidential Disclosure 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.
- *** 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.

13.4 Publicity and SEC Filings. Except as set forth in Sections 13.4.1 or 13.4.2 or unless the prior written consent of the other Party is obtained, no Party shall, except as may be required by law or regulation, 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 the opinion of any employee of the other Party. No such notice shall be required 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. Either Party may communicate to its investors information to the extent made public by the other Party.

13.4.1 Press Releases. The Parties agree that any press release or other public announcement of the execution of this Agreement (except for filings included under Section 13.4.2) 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 three (3) business 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.

13.4.2 SEC Filings. In the event that Cadence is advised by counsel to file with the Securities and Exchange Commission or the securities regulators of any state or other jurisdiction, a registration statement or 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 three (3) 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.

13.5 Survival. The obligations under this Article 13 will extend for the longer of the Term of the 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 the Original Agreement.

*** 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.

- **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 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 (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 Development Plans.

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"), as described in any Development Plan, which, collectively with the Baxter Development Deliverables, shall be referred to herein as the "Reports." The Reports may also contain references to (i) Baxter standard operating procedures, specifications, material codes and their specifications, and other information developed by Baxter prior to the Original Effective Date, 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 ("Preexisting 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 or the Original 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 Article 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. Preexisting 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 Article 13.0 of this Agreement, subject to the Baxter License under Section 14.3.2.

14.2.3 Archiving of Reports. 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.

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

14.3.3 Pre-Existing Specifications and Original Product Data. Baxter will (i) make Preexisting Specifications referenced in the Reports and Original Product Data available to Regulating Groups as directed by such Regulating Groups and as provided in Article 5.0, (ii) upon Cadence's reasonable request, provide copies of Preexisting 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 Article 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 Article 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 14.1.2 and 14.1.3 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 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 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 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 on November 1, 2015 ("**Initial Term**"), unless terminated earlier as herein provided or extended as provided in Section 19.1.2 ("**Term of the Agreement**").
- **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 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

19.2.1.2 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.

19.2.2 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.

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 Non-cancelable Costs and Expenses.** Upon termination of this Agreement, except by Cadence as a result of a breach by Baxter under Section 19.2.1.1 or 19.2.1.2, Cadence shall reimburse Baxter for all Materials ordered prior to termination and not cancelable at no cost to Baxter.
- **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 the other Party's expense if termination is initiated by a Party pursuant to Sections 19.2.1.1 through 19.2.1.2 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 19.2.1.1 or 19.2.1.2, 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 the Facility to a location specified by Cadence.

20.5 Restoration Costs of the Facility. Cadence agrees to reimburse Baxter for all reasonable costs incurred in the restoration of the Facility to its preinstallation condition, as set forth in Section 20.6, including the repair of any damage to the Facility caused by or resulting from the removal of the Cadence Owned Equipment, despite the exercise of reasonable care; *provided*, *however*, that Cadence shall not be liable for any such restoration costs with respect to any changes made to the Facility that Baxter reasonably agrees are usable by Baxter at the time of removal of the Cadence Owned Equipment.

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 the 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 the Facility, and (iii) 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 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 the 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 Initial Term and any renewals or extensions of this Agreement.

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 (Warranties of Cadence), 12.3 (Warranties of Baxter), 5.1 (Product Registration Application Ownership), and Articles 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.

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 25212 West Illinois Route 120 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: Chief Commercial Officer

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 23.1.3, "competitor" means [***].
- *** 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.

- **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 Confidential Disclosure Agreement) 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 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

Name: Theodore R. Schroeder Title: President and Chief Executive Officer

Date: January 28, 2011

/s/ Brik V. Eyre Name: Brik V. Eyre Title: General Manager Date: January 28, 2011

EXHIBIT A

PRODUCT SPECIFICATIONS

I. DESCRIPTION

The drug product is a [***] formulation of acetaminophen intended for intravenous infusion with the composition described in <u>Table 1</u>.

Table 1: Each 100mL contains Composition of Acetaminophen, Injection for Intravenous Use.

Component	Unit Formula	Quality Standard
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

II. MANUFACTURING METHOD (the "Formulation Specifications")

The Product will be manufactured according to and will meet the specification of the approved NDA 22-450.

The method of formulation is also described in Baxter Document [***] and other documents referenced therein.

The Product will be sterilized consistently to the agreement Baxter has with the FDA regarding [***] as described in Baxter DMF [***].

The Product shelf life specifications are provided in <u>Table 2</u>. For certain parameters at time of release the drug product will meet tighter limits provided in <u>Table 3</u>.

Table 2: Regulatory (Shelf Life) Specification for the Product

Attribute	Test	Reference	Acceptance Criteria
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]			[***]
[***]	[***]	[***]	[***]
[***]			[***]
[***]			[***]
[***]	[***]	[***]	[***]
[***]			[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]		[***]
[***]	[***]	[***]	[***]

Table 3: In-house Limits at Time of Release for the Product

Attribute	Test	Reference	Acceptance Criteria
[***]	[***]	[***]	[***]
[***]			[***]
[***]			[***]
[***]	[***]	[***]	[***]
[***]			[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

^{***} 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.

III. CONTAINER CLOSURE SYSTEM (the "Container")

Acetaminophen, injection for intravenous use 1,000 mg/100 mL (10 mg/mL) is packaged in [***]. The details of the container closure system are provided in <u>Table 4</u>. The vials will be labeled with a hanger style label. The content of the label will be as approved in NDA 22-450.

Table 4: Container Closure System

Component	Material	Supplier
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

IV. PACKAGING

Twenty-four vials will be packaged in a carton. The carton will be labeled according to the approved NDA 22-450 and contain one package insert with wording approved in NDA 22-450.

EXHIBIT B

API SPECIFICATIONS

NDA 22-450 Specification Limits for Acetaminophen

TEST	TEST METHOD	LIMITS
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

^{***} 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 C MINIMUM BATCH SIZE AND MANUFACTURING FEE

- A. **Minimum Batch Size:** As of the Effective Date, the "**Minimum Batch Size"** for the Product is [***] vials.
- B. **Manufacturing Fee:** The "**Manufacturing Fee**" for the Product shall be as set forth below:

		[***]		
	[***]			
	[***]	[***]	[***]	[***]
[***]	[***]	-		
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]				
[***]				

^{***} 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 D

COST OF API AND METHODOLOGY FOR CALCULATING MANUFACTURING YIELD LOSSES

[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

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EXHIBIT E

BAXTER OWNED EQUIPMENT

[***]

EXHIBIT F

CADENCE OWNED EQUIPMENT

The following list details the Cadence Owned Equipment as of the Effective Date. Cadence may amend this list from time to time by providing written notice to Baxter as follows:

Baxter Healthcare Corporation BioPharma Solutions 25212 West Illinois Route 120 Round Lake, Illinois 60073 Attention: General Manager

Fax No.: 847-270-3410

[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

^{***} 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.

[***]	[***]	[***]
	[***]	[***]
	[***]	[***]
	[***]	[***]
	[***]	[***]
	[***]	[***]
	[***]	[***]
	[***]	[***]
	[***]	[***]
	[***]	[***]
	[***]	[***]
	[***]	[***]
][***]	[***]

^{***} 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 G

CONFIDENTIAL DISCLOSURE AGREEMENT

[***]

EXHIBIT H DEVELOPMENT PLAN TEMPLATE

DEVELOPMENT PLAN #[__]

DESCRIPTION: [Insert purpose of Development Plan] **DATE:**

Once executed, this Development Plan # [__], shall be incorporated by reference as part of the Amended & Restated Development & Supply Agreement between Cadence Pharmaceuticals, Inc. and Baxter Healthcare Corporation dated January [__], 2011 (the "Agreement").

APPROVALS

CADENCE APPROVALS	BAXTER APPROVALS	
(Signature/Date)	(Signature/Date)	
(Printed Name/Title) and	(Printed Name/Title) and	
(Legal Signature/Date)	(Contract Management Signature/Date)	
(Printed Name/Title)	(Printed Name/Title)	
	TABLE OF CONTENTS	
Purpose of the Development Pla	n	
Scope of Activities		
Functional Assessments		
Pricing		
Other		
I. PURPOSE OF THE DEVELOPM	ENT PLAN	
By this Development Plan, Cadence ar	nd Baxter intend to conduct the following development project [outline high level description of the purpose].	
II. SCOPE OF ACTIVITIES		
Scope of the Development Plan	By this Development Plan, Cadence and Baxter intend to [outline scope of the activities.] [Formulation and analytical development, Specifications (API and Product Specifications), Facility improvements, Equipment/material purchases, clinical production, stability studies, pre-commercial activities.]	
Documentation/ Materials to be Provided by Baxter	Baxter will be responsible for or otherwise provide: —	
Documentation/ Materials to be Provided by Cadence	Cadence will be responsible for or otherwise provide:	
Baxter Development Deliverables		
Cadence Development		

Deliverables

III. FUNCTIONAL ASSESSMENT and REVIEW

Regulatory Strategy Other [The current Regulatory Plan is not impacted by this Development Plan.]

IV. PRICING

Description

Price

Outline description of activities to be performed under this Development Plan

IV. OTHER [Example: Cadence Owned Equipment, Baxter Owned Equipment.]

EXHIBIT I

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 API Specifications set forth in Exhibit B, as amended by Cadence from time to time.

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

The term "Applicable Laws" will mean all laws, ordinances, rules and regulations within the Territory applicable to the manufacture of the Product by Baxter, and the obligations of Baxter or Cadence thereunder, as the context requires, including, without limitation, (i) all applicable federal, state and local laws and regulations of each jurisdiction within the Territory; (ii) the FD&C Act; (iii) the cGMPs; and (iv) all applicable environmental and health and safety laws.

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 "Batch Disposition Certificate" will mean the document signed by Baxter and provided to Cadence that sets forth Baxter's recommendation to release a batch.

The term "Baxter Development Deliverables" will have the meaning set forth in Section 4.2.1.

The term "Baxter Inventions" will have the meaning set forth in Section 14.1.3.

The term "Baxter Owned Equipment" will have the meaning set forth in Section 9.2.

The term "Baxter License" will have the meaning set forth in Section 14.3.2.

The term "Cadence Development Deliverables" will have the meaning set forth in Section 4.2.1.

The term "Cadence Owned Equipment" will have the meaning set forth in Section 9.3.

The term "Cadence Inventions" will have the meaning set forth in Section 14.1.2.

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 "Capacity Increase Development Plan" will have the meaning set forth in Section 4.1.2.

The term "Cadence Product License" will have the meaning set forth in Section 14.3.1.

The term "Commercially Reasonable Efforts" will mean 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 "Communications" will have the meaning set forth in Section 5.3.

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 "**Confidential Disclosure Agreement**" will mean the two-way disclosure agreement, effective April 6, 2006, a copy of which is attached to this Agreement as Exhibit G.

The term "Confidential Information" will have the meaning set forth in the Confidential Disclosure Agreement.

The term "Container" will mean the container portion of the Product, as described in <u>Exhibit A</u>, <u>Section III</u>, as may be amended from time to time in accordance with the Quality Agreement.

The term "Contract Year" will mean the twelve (12) consecutive month period beginning on November 1, 2010, and each subsequent twelve (12) consecutive month period thereafter.

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 "Damages" will have the meaning set forth in Section 15.1.

The term "**Deficiency Notice**" will have the meaning set forth in Section 10.2.

The term "Development Plan" will have the meaning set forth in Section 4.1.3.

The term "DMF [***]" means Baxter's Type III Drug Master File Number [***].

The term "**Drug Product Manufacturing Process**" will have the meaning set forth in Section 10.8.

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 6.3.

The term "Equipment Failure Event" will have the meaning set forth in Section 9.5.

The term "Facility" will mean Baxter's manufacturing facility in Cleveland, Mississippi.

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, 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 the Manufacturing Method for the Product, as described in <u>Exhibit A, Section II</u>, as may be amended from time to time in accordance with the Quality Agreement.

The term "Improvements" shall have the meaning set forth in Section 7.4.

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 "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 "Joint Inventions" will have the meaning set forth in Section 14.1.4.

The term "Joint Patent Applications" will have the meaning set forth in Section 14.4.2.

The term "Line 1" will mean the Product manufacturing line in operation as of the Effective Date.

The term "Line 2" will mean a second Product manufacturing line planned for installation at the Facility.

The term "LOI" will have the meaning set forth in Section 1.0.

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 C.

The term "Materials" shall mean (i) all raw materials, components, work-in-process and other ingredients required to manufacture the Product except for the API, and (ii) all packaging materials used in the manufacture, storage and shipment of Product.

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

The term "Minimum Batch Size" will have the meaning set forth in Exhibit C.

The term "Minimum Purchase Requirements" will have the meaning set forth in Section 6.2.2.

The term "NDA" will mean 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 the Facility.

The term "**Original Agreement**" will have the meaning set forth in Section 1.0.

The term "**Original Effective Date**" shall mean July 18, 2007.

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 "Preexisting 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 Manager" will have the meaning set forth in Section 3.

The term "**Product Specifications**" will mean the Product Specifications set forth in <u>Exhibit A</u>, as amended from time to time in accordance with the Quality Agreement.

The term "Quality Agreement" will mean the Quality Agreement executed by the Parties effective December 18, 2007, as amended from time to time by the mutual agreement of the Parties.

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 Submissions" will mean those applications and filings for the Product 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, any 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 mean Cadence's actual requirements for the Product for use or sale in the Territory.

The term "**Routine Maintenance**" will mean the maintenance to be performed by Baxter based on a preventative maintenance schedule to be agreed upon within thirty (30) days following the Effective Date by Cadence and Baxter, as amended from time to time upon the mutual agreement of the Parties.

The term "Senior Executives" will have the meaning set forth in Section 3.2.

The term "Specified Equipment" will mean the Cadence Owned Equipment identified with an asterisk in Exhibit F.

The term "Steering Committee" will have the meaning set forth in Section 3.2.

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

The term "Territory" will mean the United States.

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.