# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

# FORM 8-K

# **CURRENT REPORT**

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

Date of Report (Date of earliest event reported) December 1, 2010

# **Cadence Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) 001-33103 (Commission File Number) 41-2142317 (IRS Employer Identification No.)

12481 High Bluff Drive, Suite 200 San Diego, California 92130 (Address of principal executive offices, including zip code)

(858) 436-1400 (Registrant's telephone number, including area code)

Not applicable

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

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

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

D 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 December 1, 2010, Cadence Pharmaceuticals, Inc. (the "Company," or "Cadence") entered into a supplemental Supply Agreement (the "Agreement") with Lawrence Laboratories ("LL"), an indirect wholly-owned subsidiary of Bristol-Myers Squibb Company ("BMS") for the manufacture of commercial supplies of the finished drug product for OFIRMEV<sup>TM</sup> (acetaminophen) injection (the "Product"), for sale and distribution by Cadence in the United States and Canada.

The Agreement is intended to complement Cadence's existing supply arrangement for OFIRMEV with Baxter Healthcare Corporation ("Baxter"), and Baxter will continue as the primary supplier for the Product.

Bristol-Myers Squibb Srl ("BMS Anagni"), an indirect subsidiary of BMS located in Anagni, Italy, will manufacture the Product on behalf of LL. Cadence believes that the geographic diversification of the Company's manufacturing operations afforded by the arrangement with LL supports its corporate risk management objectives. BMS Anagni also currently manufactures intravenous acetaminophen for sale and distribution by BMS and its affiliates in a number of countries outside of the U.S. and Canada.

Following the execution of the Agreement, Cadence submitted a supplemental new drug application ("sNDA") to the U.S. Food and Drug Administration ("FDA"), seeking the approval of the BMS Anagni facility as an additional manufacturing site for OFIRMEV. The Company expects that the successful completion of an FDA inspection of the BMS Anagni facility will be required prior to approval of the submission, and estimates a four to six-month review period.

Pursuant to the terms of the Agreement, LL will receive from the Company a set price for the Product purchased, which prices may be adjusted by LL, subject to specified limitations. In addition, Cadence is obligated to purchase a minimum number of units each year following regulatory approval of Product manufactured by LL, or pay LL an amount equal to the per-unit purchase price less LL's average material and direct labor costs for the Product, multiplied by the amount of the shortfall.

The Agreement also requires Cadence to pay LL for any validation batches required by the Company, not to exceed a specified rate, and for all additional services requested to support the development and submission of the sNDA for the Product, at a specified hourly rate.

The Agreement has an initial term that ends upon the 36-month anniversary of the date on which the sNDA is approved, unless the Agreement is terminated sooner: (a) by the mutual agreement of the parties, (b) by either party for convenience following eighteen months' prior written notice of termination to the other party, (c) upon the termination of Cadence's license agreement for the product with BMS, or (d) upon the dissolution or termination of Cadence, other than in connection with or following the assignment of the Agreement. In addition, either party may terminate the Agreement: (y) within 60 days, after written notice in the event of a material uncured breach of the Agreement by the other party, or (z) immediately, if the other party becomes insolvent or admits in writing its inability to pay its debts as they become due, files a petition for bankruptcy, makes an assignment for the benefit of its creditors or has a receiver or other court officer appointed for its properties or assets.

If the Agreement is terminated by Cadence for its convenience or by LL due to Cadence's material breach of the agreement, Cadence will reimburse LL for: (a) any product ordered under a firm order and received by the Company, and (b) any inventory of materials used to manufacture the Product that are specific to the Product and that LL is unable to reasonably utilize. Additionally, the Company's minimum purchase requirement for the year in which the termination takes effect will be reduced proportionally, and Cadence will not be required fulfill the minimum purchase requirement for any subsequent contract year. If the Agreement is terminated for any reason other than by Cadence for its convenience or by LL due to Cadence's material breach of the agreement, Cadence will not be required to reimburse LL for any inventory of materials used to manufacture the Product, and will have no obligation to purchase the minimum purchase requirement for the year in which the termination takes effect, or for any subsequent contract year.

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

#### Forward-Looking Statements

Cadence cautions you that statements included in this report that are not a description of historical facts are forward-looking statements. Such forward-looking statements include statements regarding: Cadence's belief that entering into the Agreement will introduce geographic diversification, mitigate risk and complement its existing supply arrangement; and the anticipated time for review of the sNDA. All such forward-looking statements are based on Cadence's current beliefs and expectations, and should not be regarded as a representation by Cadence that any of its plans will be achieved. Actual results may differ materially from those set forth in this report due to the risks and uncertainties inherent in the company's business, including, without limitation: our dependence entirely upon our contract manufacturers to produce OFIRMEV; our ability to ensure an adequate and continued supply of OFIRMEV to successfully launch commercial sales or meet anticipated market demand; the potential that our contract manufacturers will fail to meet our requirements for OFIRMEV, or fail to fully comply with GMP regulations, in which case we could lose potential revenues; the risk of early termination of our agreements with either of our contract manufacturers; the potential that any failure to comply with applicable regulations may result in a delay or suspension of approval of the sNDA relating to the BMS Anagni facility as well as potential for fines and civil penalties, suspension of production, or product seizure or recall; and other risks detailed in Cadence's periodic public filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement and Cadence undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof. This caution is made under the safe harbor provis

#### Item 9.01 Financial Statements and Exhibits

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(d) Exhibits.

Number	Description of Exhibit
10.1†	Supply Agreement between Lawrence Laboratories and Cadence Pharmaceuticals, Inc.

\* 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: December 2, 2010

#### EXHIBIT INDEX

# Exhibit No. Description 10.1† Supply Agreement between Lawrence Laboratories and Cadence Pharmaceuticals, Inc.

<sup>†</sup> 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.

# SUPPLY AGREEMENT

# between

#### LAWRENCE LABORATORIES

and

# CADENCE PHARMACEUTICALS, INC.

effective as of December 1, 2010

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# EXHIBITS

Exhibit A:	Specifications
Exhibit B:	Initial Forecast

#### SUPPLY AGREEMENT

This Supply Agreement (the "<u>Agreement</u>") is entered into and is effective as of December 1, 2010 (the "<u>Effective Date</u>") by and among Lawrence Laboratories, an indirect wholly-owned subsidiary of Bristol-Myers Squibb Company ("<u>BMS</u>") and a corporation organized under the laws of Ireland with its registered office at Unit 12, Distribution Centre, Shannon Industrial Estate, Shannon, County Clare, Ireland ("<u>LL</u>"), and Cadence Pharmaceuticals, Inc., a Delaware corporation having an address at 12481 High Bluff Drive, Suite 200, San Diego, California 92130 ("<u>Cadence</u>"). LL and Cadence are sometimes collectively referred to herein collectively as the "<u>Parties</u>" and each individually as a "<u>Party</u>."

#### RECITALS

WHEREAS, Cadence holds certain license rights in intellectual property relating to the Product (as defined below) in the United States and Canada pursuant to that certain IV APAP Agreement dated February, 2006, between BMS and Cadence (the "<u>IV APAP Agreement</u>"), which sublicenses to Cadence certain intellectual property rights with respect to the United States and Canada under that certain License Agreement dated December 23, 2002 between SCR Pharmatop, a civil law partnership organized under the laws of France, having its head office's address at 10, Square St. Florentin, 78150 Le Chesnay, France, recorded with the Register of Commerce and Companies of Versailles under No. 407552702, and BMS (the "<u>Pharmatop License Agreement</u>") and licenses to Cadence certain rights to use patents and know-how of BMS in the same jurisdictions;

WHEREAS, LL has made arrangements for one of its Affiliates (as defined below) located in Italy to manufacture the Product for supply to Cadence pursuant to this Agreement;

WHEREAS, LL or its Affiliate holds certain license rights in intellectual property relating to the Product (as defined below) in Italy entitling LL or its Affiliate to use such intellectual property to manufacture the Product in Italy for supply to Cadence pursuant to this Agreement;

WHEREAS, LL or its Affiliates have expertise in manufacturing the Product; and

WHEREAS, Cadence desires to purchase, and LL desires to supply from its Affiliate's facility in Italy (or such other facility as LL may determine in accordance with this Agreement), Cadence's requirements for the Product for use in the Territory (as defined below).

#### AGREEMENT

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

#### ARTICLE 1

#### DEFINITIONS

1.1 Defined Terms. As used in this Agreement, the following terms shall have the following meanings:

"Affiliate" of a Party means any corporation, firm, partnership or other entity that directly or indirectly Controls, is Controlled by or is under common Control with such Party.

"Agreement" has the meaning set forth in the Introductory Paragraph.

"<u>Applicable Law</u>" means any applicable federal, state, local or foreign statute, law, ordinance, rule or regulation, judicial order or industry standard imposed by regulation or law, including without limitation the laws of, and regulations promulgated under, the FDCA or the Canadian equivalent of the FDCA.

"BMS" has the meaning set forth in the Introductory Paragraph.

"Business Day" means any day other than a Saturday, a Sunday or a United States Federal, EU, Irish or Italian holiday.

"Cadence" has the meaning set forth in the Introductory Paragraph.

"Cadence Party" has the meaning set forth in Section 6.1.

"CGMP" means all current good manufacturing practices under 21 C.F.R. 210, as amended from time to time, or any successor regulation.

"<u>Claim</u>" means any claim (including without limitation, product liability claims, strict liability or tort claims and intellectual property infringement claims), action, suit, governmental investigation or other proceedings made or brought by or on behalf of a Third Party against any Cadence Party or any LL Party, as the case may be, including without limitation enforcement actions by the FDA or other applicable Drug Regulatory Authorities and claims for infringement of intellectual property and for bodily injury, death or property damage.

"Confidential Information" has the meaning set forth in the IV APAP Agreement.

"<u>Contract Year</u>" will mean the twelve-month period beginning on the first day of the month following the date on which the Facility NDA is approved by FDA, and each successive twelve-month period thereafter for the duration of this Agreement.

"<u>Control</u>" means (a) with respect to Technology or technical information, the possession by a Party of the ability to grant a license or sublicense of such Technology or technical information as provided herein without violating the terms of, or requiring a consent under, any agreement or arrangement between such Party and any Third Party and (b) when used with respect to any Person means the power to direct the management and policies of such Person, directly or indirectly, whether through the ownership of voting securities, by contract, or otherwise. "<u>Controlled</u>" and "<u>Controlling</u>" shall have correlative meanings.

"Demand" has the meaning set forth in Section 7.2.

"Dispute" has the meaning set forth in Section 7.1.

"Dollar" or "<u>\$</u>" means United States dollars, the lawful currency of the United States.

"Drug Regulatory Authority" means any governmental authority or instrumentality with responsibility for granting any licenses, approvals, authorizations (e.g., the NDA) or granting pricing and/or reimbursement approvals necessary for the marketing and sale of pharmaceutical products in any regulatory jurisdiction.

"Effective Date" has the meaning set forth in the Introductory Paragraph.

"EMA" means the European Medicines Agency, or any successor agency.

"Facility" has the meaning set forth in Section 3.9.

"Facility NDA" means an NDA filed with the FDA by Cadence with respect to Product to be manufactured under this Agreement.

"FDA" means the United States Food and Drug Administration or any successor agency.

"FDCA" means the Federal Food, Drug & Cosmetics Act, 21 U.S.C. 321 et seq., any amendments or supplements thereto, or any regulations promulgated or adopted thereunder.

"Firm Order" has the meaning set forth in Section 3.2(a).

"Force Majeure" means any circumstances that are not within the reasonable control of the Person affected thereby, including without limitation an act of God, terrorist attack, war, insurrection, riot, strike or labor dispute, shortage of materials, fire, explosion, flood, government requisition or allocation, breakdown of or damage to plant, equipment or facilities (to the extent that, in the event of a breakdown only, such plant,

equipment or facilities were reasonably maintained), mandated requisition or allocation, interruption or delay in transportation, fuel supplies or electrical power, embargo, boycott, order or act of civil or military authority.

"Forecast" has the meaning set forth in Section 3.1.

"Incoterms" means the year 2000 edition of the official International Chamber of Commerce's rules for the interpretation of trade terms or any successor set of rules, guidelines or terms developed thereunder.

"Indemnified Party" has the meaning set forth in Section 6.3.

"Indemnifying Party" has the meaning set forth in Section 6.3.

"Initial Forecast" has the meaning set forth in Section 3.1.

"IV APAP Agreement" has the meaning set forth in the Recitals.

"LL" has the meaning set forth in the Introductory Paragraph.

"LL Party" has the meaning set forth in Section 6.2.

"Losses" means, collectively, any and all liabilities, damages, reduction in value, costs, expenses, including reasonable fees and disbursements of counsel and any consultants or experts and expenses of investigation, obligations, liens, assessments, court costs, arbitration or mediation fees, judgments, fines and penalties imposed upon or incurred by an Indemnified Party (including, until such time as the Indemnifying Party assumes control of a given Claim, reasonable attorneys' fees and costs of litigation pertaining to such Claim).

"Materials" has the meaning set forth in Section 2.5(a).

"Minimum Purchase Requirement" has the meaning set forth in Section 2.3.

"<u>NDA</u>" means a new drug application or an abbreviated new drug application, including any amendments or supplements thereto, filed by Cadence with the FDA pursuant to the FDCA, or any comparable filing with any Drug Regulatory Authority in Canada, and includes any Common Technical Document for the Registration of Pharmaceuticals for Human Use filed with the FDA or any other Drug Regulatory Authority in the Territory.

"Parties" has the meaning set forth in the Introductory Paragraph.

"Party" has the meaning set forth in the Introductory Paragraph.

"Person" means any individual, firm, corporation, partnership, limited liability company, trust, joint venture, governmental authority or other entity.

"Pharmatop License Agreement" has the meaning set forth in the Recitals.

"Price Adjustment Method" has the meaning set forth in Section 2.2(d).

"<u>Product</u>" means the sterile, non-pyrogenic formulation of paracetamol (acetaminophen) intended for intravenous infusion with a concentration of 10 mg/ml in 100 ml vials as more particularly set forth in the Specifications. Product shall be packaged with 12 vials per shrink-wrapped pack. Product will be available in 12 vials per case (single pack) or 24 vial per case (two packs).

"Quality Agreement" has the meaning set forth in Section 3.8.

"Reconciliation Payment" has the meaning set forth in Section 2.3(b).

"Reconciliation Price" has the meaning set forth in Section 2.3(b).

"<u>Regulatory Approval</u>" means with respect to the Product in any regulatory jurisdiction in the Territory, approval from the applicable Drug Regulatory Authority sufficient to market and sell the Product in such jurisdiction.

"Specifications" means the specifications set forth on Exhibit A, as amended by the Parties pursuant to the terms of the Quality Agreement.

"Supply Price" has the meaning set forth in Section 2.2.

"Supply Term" means the period beginning on the first day of the first Contract Year and terminating thirty six (36) consecutive months later, unless extended by the mutual agreement of the Parties.

"<u>Technology</u>" means and includes all inventions, discoveries, improvements, trade secrets, know-how, processes, procedures, research records, records of inventions, test information, formulae, drawings, specifications, instructions, techniques, data, market surveys and other similar proprietary methods, materials or property, whether or not patentable, relating to the Product, including but not limited to (a) samples of, methods of production or use of, and structural and functional information pertaining to, chemical compounds, proteins or other biological substances, (b) data, formulations, techniques and know-how, and (c) rights under patents, patent applications, and copyrights.

"Territory" means the United States (including Puerto Rico and all U.S. possessions and territories) and Canada.

"Third Party" means a Person who or which is neither a Party nor an Affiliate of a Party.

#### ARTICLE 2

#### SUPPLY OF PRODUCTS

#### 2.1 Supply and Purchase.

(a) During the Supply Term and upon the terms and conditions set forth in this Agreement, LL shall, or shall cause its Affiliates to, manufacture, or cause the manufacture of, and supply to Cadence certain quantities of the Product ordered pursuant to Firm Orders hereunder, subject to variations permitted by Section 3.2(a). Cadence shall purchase from LL and its Affiliates all of the Product ordered by Cadence pursuant to Firm Orders hereunder. LL shall have no obligation to accept any Firm Order that calls for the delivery of the Product following the end of the Supply Term.

(b) The Product shall be in finished vials, labeled and packed, at Cadence's option, in cases of 12 or 24 vials per case.

#### 2.2 Supply Price

The "Supply Price" for the Product shall be as follows:

(a) First Contract Year:

Number of vials ordered during First Contract Year*	First Contract Year Supply Price for Per 12-pack**	First Contract Year Supply Price for Per 24-pack**
[***]	\$[***]	\$[***]
[***]	\$[***]	\$[***]
[***]	\$[***]	\$[***]

\* Pricing may not be applied retroactively. (E.g., [\*\*\*]) Price breaks effective on full lot purchases subsequent to meeting volume requirement.

(i) If the First Contract Year commences on or after [\*\*\*], a pricing adjustment in accordance with the Price Adjustment Method may be applied; *provided, however*, that if the First Contract Year commences on or after [\*\*\*] as a result of [\*\*\*], the Price Adjustment Method may not be applied.

(b) Second Contract Year:

No. of vials ordered	Supply Price Per 12-pack	Supply Price Per 24-pack
[***]	\$[***]	\$[***]

\*\*\* 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.

- (ii) If the Second Contract Year commences on or after [\*\*\*], a pricing adjustment in accordance with the Price Adjustment Method may be applied; *provided, however*, that if the Second Contract Year commences on or after [\*\*\*] as a result of [\*\*\*], the Price Adjustment Method may not be applied.
- (c) Third Contract Year:

No. of vials ordered	Supply Price Per 12-pack	Supply Price Per 24-pack
[***]	\$[***]	\$[***]

(i) A pricing adjustment in accordance with the Price Adjustment Method may be applied upon first day of the Third Contract Year.

(d) Price Adjustment Method: The "Price Adjustment Method" is reflected in the following formula:

The Supply Price may be increased or decreased based upon [\*\*\*].

All costs used to calculate changes to the Supply Price shall be converted into United States dollars using the applicable rate of exchange quoted by Reuters Ltd. prevailing at 3:00 p.m. (GMT) on the last Business Day of the applicable Contract Year.

LL shall provide documentation reasonably satisfactory to Cadence to support each such Supply Price increase or decrease including, without limitation, copies of supplier's invoices.

(e) Payment: The Supply Price and payments shall be in U.S. Dollars.

#### 2.3 Minimum Purchase Requirements.

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(a) Subject to Sections 8.2(a) and 8.2(b) of this Agreement, Cadence shall purchase the following quantities of the Product during the periods referenced below (the "<u>Minimum Purchase Requirement</u>"):

- First Contract Year = [\*\*\*] vials of Product; and
  - Second and Third Contract Years = [\*\*\*] vials of Product.

(b) In the event that the total number of Product vials ordered by Cadence from LL (based on Firm Orders placed) in a given Contract Year is less than the Minimum Purchase Requirement for that Contract Year, Cadence shall pay LL a reconciliation payment

<sup>\*\*\*</sup> 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.

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within [\*\*\*] from the date of receipt of LL's valid invoice for such payment, calculated according to the formula set forth below (the "Reconciliation Payment"):

The amount of the Reconciliation Payment shall be equal to:

[\*\*\*]:

The "Reconciliation Price" for a given Contract Year shall be equal to:

[\*\*\*].

The Reconciliation Price shall be calculated [\*\*\*].

2.4 <u>Miscellaneous Fees</u>. Cadence shall pay LL for all additional services requested by Cadence in support of the development and submission of the Facility NDA and subsequent commitments to FDA at a rate of \$[\*\*\*]. Cadence shall also pay LL for any new validation batches that may be required at a price not to exceed \$[\*\*\*] per batch. In each case, LL shall provide Cadence with a written estimate of all such miscellaneous fees at least [\*\*\*] in advance of the commencement of work (or as mutually agreed), and the Parties agree to work together to expeditiously resolve any disagreements as to the scope or costs of such services. No such services shall be commenced until LL receives Cadence's valid purchase order covering such services. In the event that the Parties are unable to reach agreement, the matter will be referred for resolution in accordance with Section 7.1 of this Agreement. LL shall invoice Cadence for the foregoing fees in accordance with the principles set forth in Section 3.5.

#### 2.5 Additional Supply Provisions

(a) <u>Materials</u>. LL shall procure all materials required to produce the Product, including without limitation the active pharmaceutical ingredient (acetaminophen) (collectively, the "<u>Materials</u>") at such times, and in such amounts as required for LL to timely fulfill the Firm Orders. Both Parties agree to work together to reduce lead time for orders and deliveries of the Materials. LL shall obtain the Materials only from suppliers listed in the NDA for the Product, and shall perform all testing of Materials required by the NDA or Quality Agreement.

(b) <u>Label Copy</u>. All label copy and changes thereto on the Product label shall be the responsibility of Cadence, and LL shall affix to the Product labels in the form most recently approved by Cadence.

(c) <u>Stability Studies</u>. LL shall perform, on an on-going basis, all stability studies required by the Specifications, Applicable Laws, the NDA for the Product, and the Quality Agreement, at no additional cost to Cadence.

\*\*\* 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.

(d) <u>Reference Standards</u>. Unless available through the United States Pharmacopeia, Cadence shall provide, without charge to LL, analytical reference standards for the Product in quantities reasonably required by LL to perform its obligations under this Agreement.

(e) <u>Cadence Access to Facility</u>. LL shall use its commercially reasonable efforts to provide Cadence's employee or contractor with reasonable access to the Facility at mutually agreeable times in order to facilitate such activities as batch record review and Product release. Any such employee or contractor of Cadence shall comply fully with the Facility's applicable safety, security and GMP procedures,

#### ARTICLE 3

#### TERMS AND CONDITIONS OF PURCHASE AND SALE

3.1 <u>Forecasts</u>. Within [\*\*\*] after the Effective Date, Cadence shall provide to LL Cadence's initial forecast of its requirements for the Product that Cadence expects to order for delivery during the [\*\*\*] following the Effective Date (the "<u>Initial Forecast</u>"). Subsequently, prior to the first day of each calendar month during the Supply Term, Cadence shall deliver to LL an updated forecast setting forth its requirements for the Product that Cadence expects to order for delivery during the [\*\*\*] period beginning on the first day of such calendar month. Each such forecast is referred to herein as, a "<u>Forecast</u>" and the Parties hereto acknowledge and agree that, except for the first [\*\*\*] of each such Forecast, such Forecast shall not be binding on Cadence.

Notwithstanding the foregoing, in the event that the Facility NDA is not approved by the date on which the Initial Forecast is provided to LL:

(a) Cadence's requirements for the Product included therein shall be delayed by a period of time equal to the length of time between the date on which the Initial Forecast is provided to LL and the date on which the Facility NDA is approved by the FDA; and

(b) The first [\*\*\*] of the Initial Forecast shall not be binding upon Cadence until such time as the Facility NDA is approved by the FDA.

#### 3.2 Ordering.

(a) Cadence shall submit to LL a written irrevocable firm purchase order for all Product to be purchased by it not later than [\*\*\*] prior to the first requested shipping date of

<sup>\*\*\*</sup> 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.

such Product (each, a "<u>Firm Order</u>"). Each such Firm Order shall include the quantity (full batches only; multiples of the minimum batch size) of the Product and the desired time and manner of shipment and the shipping destination, and shall be limited to a single Product code (i.e., 12 vials per pack or 24 vials per pack). Any Firm Order for any Product must be for a quantity equal to the minimum batch size for such Product as in effect from time to time or an integral multiple thereof. The minimum batch size in effect as of the date of this Agreement is [\*\*\*] vials of the Product ([\*\*\*] cases of 12 or [\*\*\*] cases of 24). LL shall be obligated to manufacture, supply and deliver the specified quantity of the Product in accordance with the delivery schedule set forth in each Firm Order, however, the Parties agree that the actual number of vials successfully manufactured by LL for any batch of the Product may be within a range of plus or minus [\*\*\*] percent (+/-[\*\*\*]%) of the minimum batch size or of the actual number of vials ordered by Cadence pursuant to a Firm Order. The number of vials of Product supplied by LL pursuant to a Firm Order may only vary from the amount actually ordered by Cadence within such limits, and LL may ship to Cadence, and Cadence shall purchase, such greater or lesser number of vials in full satisfaction of such Firm Order, <u>provided</u> that Cadence shall only be required to purchase such number of vials actually supplied to Cadence. LL shall provide to Cadence as to whether LL anticipates that it will be unable to deliver the specified quantity of Product within the timeframe set forth in the Firm Order. In the event LL fails to so notify Cadence, the quantity and time specified in each such Firm Order shall be deemed accepted by LL. Firm Orders may be amended by mutual agreement of the Parties, with no resulting penalty or cost to Cadence. LL shall exercise commercially reasonable efforts to comply with changes to Firm Orders that Cadence may request, but shall not be liable for its in

(b) No terms and conditions contained in any purchase order, acknowledgment, invoice, bill of lading, acceptance or other preprinted form issued by either Party shall be effective to the extent they are inconsistent with or modify the terms and conditions contained herein.

3.3 <u>Shipping Document</u>. Each shipment of Product shall include a certificate of analysis and a packing slip that describes the Product, the date of manufacture, traceable lot or batch number(s), quantities, shipment date and destination and such additional information as the Parties may agree in writing from time to time.

#### 3.4 Delivery, Title, and Shipping.

(a) Delivery of Product shall be FCA (Incoterms) Anagni, Italy, which port of departure (maritime or air) shall be specified by Cadence. LL shall arrange for shipping and insurance in the manner customarily arranged for its own products from the point of manufacture to the port of departure and shall arrange for Italian export clearances, but Cadence shall bear the

<sup>\*\*\*</sup> 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.

cost of such shipping and insurance, any special packing expenses and export or customs agents, all of which shall be included in LL's invoice and paid by Cadence in accordance with Section 3.5. Cadence shall arrange for loading, shipment, insurance from the port of departure to the ultimate destination and import customs clearances at the destination country, and Cadence shall be responsible for all loading charges, freight, insurance, import customs clearances and other shipping expenses from such port of departure to the ultimate destination. Title to the Product and risk of loss, delay or damage in transit for Product purchased by Cadence shall pass to Cadence when a shipment of the Product is placed at the disposal of Cadence's carrier at the port of departure. Cadence shall cause its carrier to inspect all Product for physical damage prior to shipment, and Cadence shall promptly notify LL of any such physical damage. Cadence shall bear the cost of all such pre-shipment inspection. LL and its Affiliates shall not have any responsibility for any loss or damage to any Product that occurs after LL or its export or customs agent places the Product at the disposal of Cadence's carrier, nor shall any loss or damage to any Product that occurs following such placement at the disposal of Cadence's carrier obviate Cadence's obligation to purchase and pay for such Product. Without limiting LL's right to recover the full invoiced amount for the Product and as partial security therefor, Cadence shall cause each shipment of Product to be insured for the full invoiced amount of each shipment. Cadence shall provide to LL proof, satisfactory to LL, of such insurance.

The ultimate destination country of each shipment hereunder shall be in the Territory.

(b) LL shall place the Product at the disposal of Cadence's carrier at port of departure (maritime or air) for shipment to Cadence or its designee, appropriately labeled with a traceable lot or batch number and packaged for shipping in the standard commercial packaging materials customarily used by LL not later than the shipping date requested by Cadence in its Firm Order. If Cadence requests a first shipping date that is less than [\*\*\*] after the delivery to LL of the applicable Firm Order, LL shall use reasonable commercial efforts to meet such earlier delivery date, but LL shall not be in breach of this Agreement for failing to meet such earlier delivery date. If LL or its Affiliate is unable to place any shipment at the disposal of Cadence's carrier by the date described in the first sentence of this paragraph, in addition to any other remedies available to Cadence pursuant to this Agreement or otherwise, LL shall provide Cadence with updated delivery information (including estimated delivery date(s)) in writing on a weekly basis until such shipment has been made available to Cadence's carrier.

(c) Cadence shall make arrangements with a carrier to pick up each shipment of Product at the designated port of departure (maritime or air) and to transport such shipment of Product to Cadence or its designee. Cadence shall notify LL in advance in writing of the name of the carrier and shall provide such other information as may be necessary for LL to place the Product at the disposal of such carrier at the port of departure. Cadence shall have sole responsibility for the import of the Product into the Territory and for obtaining all import and import-related customs permits and clearances; *provided, however*, that LL and its Affiliates

<sup>\*\*\*</sup> 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.

shall promptly provide to Cadence all information and documentation reasonably requested by Cadence in order to obtain such permits and clearances.

(d) In the event of any shortage of supply of Product due to Force Majeure, LL shall allocate its available supply of Product between it and its Affiliates, its and its Affiliates' other customers and Cadence on a pro rata basis based on the aggregate firm orders for the Product, which allocation shall be determined by LL in good faith.

#### 3.5 Invoicing and Payment.

(a) LL shall invoice Cadence for the Product in Dollars at the time of shipment. Each invoice shall include the invoice number, the Firm Order number, unit price and total price of the Product contained in the shipment.

(b) Cadence shall pay LL within [\*\*\*] after the receipt of any undisputed invoice. All payments to be made hereunder to LL shall be made in Dollars by wire transfer of immediately available funds to such bank account as may be designated by LL in writing from time to time, unless the Parties agree to settle such payments through other means. In the event Cadence disputes any invoice, Cadence shall pay any undisputed amount as and when due hereunder and shall pay the additional amount, if any, owed with respect to such invoice not later than [\*\*\*] following the resolution of such dispute.

(c) Any undisputed payment not made as and when due shall bear interest at the rate of [\*\*\*] percent ([\*\*\*]%) per annum, compounded daily, from the due date to the date of payment. In addition to but without limiting the preceding sentence, LL shall have the right to suspend future shipments of Product to Cadence if LL does not receive payment within [\*\*\*] after the date of any invoice, other than invoices subject to a *bona fide* dispute. LL shall resume shipments of Product upon receiving such late payment and, if requested by LL, reasonable assurances as to payment of future invoices.

#### 3.6 Inspection; Non-Conforming Product.

(a) Cadence shall promptly inspect or cause to be inspected all shipments of Product hereunder. Within [\*\*\*] after receipt by Cadence of any shipment of Product, Cadence may reject any lot or portion thereof which, at the time LL placed the Product at the disposal of Cadence's carrier, (i) failed to conform to the Specifications, (ii) was not manufactured in full conformance with Applicable Laws (including, without limitation, U.S. cGMPs) or the terms of this Agreement, or (iii) for which the related batch record does not demonstrate conformance with the approved manufacturing process. Upon any such determination by Cadence, Cadence shall notify LL by sending LL notice of the lot or batch numbers of the rejected Product, together with an indication of the specific basis for rejection and a sample of the rejected goods.

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Notwithstanding the foregoing, if the discovery of the non-conformity of any Product could not reasonably have been discovered until after such [\*\*\*] period, Cadence shall notify LL of such non-conformity promptly following the discovery thereof. Cadence shall not be entitled to reject any shipment or any portion thereof where it can be proven that the damage to the Product occurred following the time that LL placed the Product at the disposal of Cadence's carrier, and Cadence's sole remedy shall be against the carrier or under any applicable insurance. LL shall have the right to examine and test any Product that Cadence claims to be non-conforming. If it is determined that there is any such failure to conform to Specifications at the time that LL placed the Product at the disposal of Cadence's carrier, LL and Cadence shall cooperate to determine the cause of the non-conformity.

(b) In the event that LL and Cadence do not resolve any issue where it is asserted that a batch of Product does not conform with the Specifications within [\*\*\*] after LL notifies Cadence that LL disagrees with Cadence's belief as to the non-conformity of such Product at the time that LL placed the Product at the disposal of Cadence's carrier, the Parties shall submit a sample of the disputed Product to an independent laboratory, mutually selected by the Parties, for testing, and the results of such testing shall be binding upon the Parties, absent fraud or manifest error on the part of the independent laboratory. The Party whose assertion as to the conformity or nonconformity of the Product in question is not supported by the results of the independent laboratory shall bear all costs and expenses of such testing. If the results of such testing by such independent laboratory are inconclusive, then (i) all costs and expenses of such testing shall be breat testing in equal shares and (ii) the Parties shall share equally the Supply Price of such Product and the freight, insurance and other shipping expenses, fees, duties, taxes and levies incurred by the Parties in connection therewith, and Cadence shall pay to LL one-half of such Supply Price and other items within [\*\*\*] after the receipt of such inconclusive results; and (iii) LL shall promptly replace any such Product and deliver FCA, in accordance with Section 3.4, replacement conforming Product (even if such replacement entails shipping Product subsequent to the Supply Term), which shall be purchased and paid for by Cadence in accordance with Article 2 and Section 3.5 of this Agreement.

(c) Cadence shall, as requested by LL in its sole discretion: (i) return promptly to LL at LL's expense all properly rejected Product or (ii) destroy such non-conforming Product in accordance with FDA guidelines or send such non-conforming Product to a destruction facility of LL's choice for destruction at LL's expense. Cadence shall not be required to pay LL for any Product that has been properly rejected, and LL shall reimburse or credit Cadence for the freight, insurance and other shipping expenses, fees, duties, taxes and levies for any shipment of Product that is properly rejected. LL shall promptly replace any properly rejected Product and supply to Cadence conforming Product (even if such replacement entails shipping Product subsequent to the Supply Term). Cadence shall pay the

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Supply Price and all shipping costs (which shall include the cost of returning the Product to LL and reshipping such Product to Cadence or its designee) for any Product improperly rejected.

3.7 <u>Obsolescence Charge</u>. To the extent that LL purchases inventories of materials, components or other supplies pursuant to Cadence's Forecast (based on vendor lead time), and such materials, components or other supplies become unusable as a result of a change to the Specifications requested by Cadence, [\*\*\*] such inventories that are unique to Cadence's configuration of the Product and that were purchased but unused and cannot reasonably be used by LL for any other purpose.

3.8 <u>Quality Control</u>. LL (and/or one of its Affiliates) and Cadence shall enter into a quality agreement (the "<u>Quality Agreement</u>") within [\*\*\*] following the execution of this Agreement containing quality terms consistent with Applicable Law and such other terms as are mutually satisfactory to the Parties and not inconsistent with this Agreement. LL shall comply with all of the provisions and requirements of the Quality Agreement in manufacturing, testing and supplying Product to Cadence. Any breach of the Quality Agreement shall be deemed a breach of this Agreement. In the event of any conflict between the terms of this Agreement and the Quality Agreement with respect to quality assurance or quality control matters, the terms of the Quality Agreement shall control.

3.9 <u>Change of Supplier or Facility</u>. LL may upon [\*\*\*] prior written notice to Cadence change the manufacturing facility used in the manufacturing of the Product (the "<u>Facility</u>") to another facility, provided that any such change in the manufacturing facility shall be expressly conditioned upon: (a) [\*\*\*]; (b) [\*\*\*]; (d) [\*\*\*]; and (e) [\*\*\*].

3.10 <u>Recalls</u>. Each Party shall notify the other by telephone within [\*\*\*] hours after receiving any information, request or directive giving rise to a good faith belief that a recall of any Product manufactured pursuant to this Agreement is or may be required under Applicable Law or is or may be otherwise necessary to avoid risk of injury or liability. Notwithstanding anything in this Agreement or the Quality Agreement to the contrary, Cadence shall have sole discretion over whether and under what circumstances to require the recall of the Product in the Territory, unless a Drug Regulatory Authority in the Territory issues or requests a recall or takes similar action in connection with such Product.

In the event that LL, in good faith, believes that a recall is required under Applicable Law or is otherwise necessary to avoid risk of injury, it shall inform Cadence by providing written notice thereof to Cadence specifying, in reasonable detail, the nature and all relevant circumstances giving rise to LL's belief that a recall is warranted, and information regarding the affected Product. Within [\*\*\*] following Cadence's receipt of such written notification (or sooner if exigent circumstances exist or otherwise are required in order to comply with Applicable Law), the Parties shall discuss the circumstances giving rise to such notification and

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the content of such notification, and, if so required, the timing and breadth of the recall, the strategies and notifications to be used by Cadence to effect the recall, and other related issues. In the event that LL recommends to Cadence, in good faith, that a recall of a particular batch or batches of the Product should be conducted, and Cadence declines to recall such Product, LL shall be entitled to indemnification pursuant to Section 6.2 of this Agreement.

LL and Cadence each shall maintain such traceability records as are sufficient and as may be necessary to permit a recall, product withdrawal or field correction of any Product. Each Party shall provide full cooperation and assistance to the other Party in connection with any recall as may be reasonably requested by the other Party.

(a) If a Product recall results from: (i) the failure of any Product, packaging or labeling supplied hereunder to conform to the Specifications; (ii) the failure of any Product, packaging or labeling supplied hereunder to comply with Applicable Laws or the terms of this Agreement, including the Quality Agreement, at the time the Product was delivered by LL to Cadence's carrier; (iii) any negligent, grossly negligent or willful act or omission by LL or its Affiliates, including without limitation the negligent or grossly negligent manufacture of the Product, LL shall: (x) credit to Cadence an amount equal to the total purchase price paid by Cadence to LL for the Product so recalled, plus Cadence's actual cost for direct material and direct labor furnished by Cadence or its contracting parties in connection with the manufacture of the recalled Product, (y) reimburse Cadence for all expenses associated with the conduct of the recall action (e.g. advertising, mailing, administration, travel, etc.), and (z) indemnify and hold Cadence harmless from and against any and all damages, costs or charges, lawsuits or expenses associated with or resulting from any such recall, including reasonable legal fees and disbursements.

(b) If a Product recall results from: (i) improper handling, shipping or storage of the Product after delivery by LL to Cadence's designated carrier, (ii) the inadequate or misleading nature of any text appearing on the packaging or labeling of the Product in compliance with the Specifications; (iii) any negligent, grossly negligent or willful act or omission by Cadence, or (iv) due to circumstances other than those described in Section 3.10(a), above, then LL shall have no liability with respect to the recall and Cadence shall indemnify, defend and hold LL and each other LL Indemnitee from any and all Losses suffered by such LL Indemnitee arising or related to such recall.

The rights and remedies available to each Party under this Section 3.10 are not exclusive and shall be in addition to all other right and remedies available to such Party at law and in equity.

3.11 Product Complaints. Each Party shall notify the other Parties regarding Product complaints as agreed between the Parties in the Quality Agreement.

#### 3.12 Representations, Warranties and Covenants.

(a) LL represents, warrants and covenants that the Product when delivered FCA at the designated port of departure Incoterms in accordance with Section 3.4 shall (i) conform to the Specifications; (ii) be manufactured, packaged, tested, stored, handled by it and

its Affiliates in compliance with the Specifications, this Agreement, the Quality Agreement and all Applicable Laws; (iii) be shipped to Cadence within [\*\*\*] after the date of manufacture; and (iv) at the time of that LL places the Product at the disposal of Cadence's carrier, not be adulterated or misbranded within the meaning of the FDCA. Notwithstanding the foregoing, LL does not represent, warrant or covenant against any Product becoming adulterated or misbranded within the meaning of the FDCA or ceasing to conform to the Specifications as a result of an act or omission or damage caused by Cadence or any Third Party (including any carrier of Cadence) after placement of the Product at the disposal of Cadence's carrier pursuant to Section 3.4. LL represents, warrants and covenants that LL or its Affiliate shall transfer to Cadence good and marketable title to the Product free from any and all liens, mortgages or encumbrances of any kind created by LL and its Affiliates and its and their suppliers and creditors.

(b) LL represents, warrants and covenants that it and its Affiliates hold and will continue to hold during the Supply Term sufficient rights in all manufacturing processes and Technology necessary for the manufacture and supply of the Product.

(c) LL represents, warrants and covenants that as of the date hereof it has not received written notice of any pending or threatened Claim that would interfere with LL's performance under this Agreement or that materially and adversely affects the rights and interests of Cadence hereunder.

(d) LL represents and warrants that it is duly organized, validly existing and in good standing under the laws of Ireland, and that it has not been debarred and is not subject to debarment and that it will not use in any capacity, in connection with the services to be performed under this Agreement, any person who has been debarred pursuant to Section 306 of the FDCA, or who is the subject of a conviction described in such section. LL agrees to inform Cadence in writing immediately if it or any person who is performing services hereunder is debarred or is the subject of a conviction described in Section 306, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of LL's knowledge, is threatened, relating to the debarment or conviction of LL or any person performing services hereunder.

(e) Each Party represents, warrants and covenants that the execution and delivery of this Agreement and the performance of its obligations hereunder: (i) has been authorized to enter into this Agreement by all necessary corporate action on the part of it and its shareholders, (ii) does not conflict with or violate any requirement of Applicable Law or any of its charter documents and (iii) does not conflict with, violate or breach or constitute a default or require any consent (which has not been obtained) under, any contractual obligation, license or court or administrative order by which it is bound.

<sup>\*\*\*</sup> 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.

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(f) EXCEPT AS EXPRESSLY PROVIDED IN THISAGREEMENT, NEITHER LL NOR ANY OF ITS AFFILIATES MAKES ANY REPRESENTATION OR WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, WRITTEN OR ORAL, STATUTORY OR OTHERWISE WITH RESPECT TO THE PRODUCTS (WHETHER USED ALONE OR IN COMBINATION WITH OTHER SUBSTANCES) OR ANY MANUFACTURING PROCESS USED TO MANUFACTURE ANY PRODUCTS, INCLUDING WITHOUT LIMITATION (i) ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE; (ii) ANY IMPLIED WARRANTIES ARISING FROM COURSE OF PERFORMANCE, COURSE OF DEALING OR USAGE IN THE TRADE; (iii) ANY WARRANTIES OF DESIGN OR DESCRIPTION OR ANY WARRANTY OTHERWISE CREATED BY ANY AFFIRMATION OF FACT OR PROMISE OR SAMPLE OR MODEL; (iv) AND ALL SUCH REPRESENTATIONS AND WARRANTIES WHETHER IN CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE, ARE HEREBY DISCLAIMED.

3.13 Force Majeure. No Party shall be considered to be in breach of, nor shall any Party be liable for any failure to perform its obligations under, this Agreement (other than obligations to make payments of money) by reason of Force Majeure. A Party affected by Force Majeure shall give the other Party prompt notice of any interruption of performance on account of Force Majeure, and of the resumption of such performance, and shall keep the other Party informed on a current basis as to the steps being taken to remove, and the anticipated time of removal of, the circumstances resulting in such Force Majeure. The time for performance of any obligation hereunder that is affected by Force Majeure shall be extended by the actual time of delay caused by such Force Majeure, provided that the Party affected by such Force Majeure uses commercially reasonable efforts to mitigate any such delay. Notwithstanding the foregoing, nothing in this Section 3.13 shall excuse or suspend the obligation to make any payment due under this Agreement in the manner and at the time provided herein.

#### ARTICLE 4

#### REGULATORY MATTERS

4.1 <u>Record Retention</u>. Any books and records relating to the receipt, manufacture, storage, handling or testing of any Product shall be maintained under this Agreement by a Party or its Affiliates in accordance with Applicable Law.

#### 4.2 Regulatory Matters.

(a) At all times during the Term, LL shall maintain the production facility, equipment and processes (including, without limitation, the process used in producing the Product and in performing LL's other obligations under this Agreement) in compliance with this Agreement, the Quality Agreement and all Applicable Laws (including, without limitation, cGMP, the FDA and, to the extent applicable, the EMA guidelines, employment and labor law requirements, electrical, fire and safety at work codes and regulations and guidelines issued by any applicable Drug Regulatory Authorities in the Territory). LL shall make available for inspection, upon the request of Cadence, all documentation relating to such compliance.

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(b) LL shall permit representatives of Cadence to conduct inspections from time to time at all Facilities utilized by LL and its Affiliates hereunder to manufacture the Product, as agreed between the Parties in the Quality Agreement.

(c) If either Party is notified that the Product manufactured at the Facility or the Facility will be subject to an inspection by FDA or any other Drug Regulatory Authority, such Party shall as soon as possible notify the other Party by telephone and e-mail of its receipt of such notification. LL shall provide Cadence copies of all Drug Regulatory Authority-issued inspection observation reports (including, without limitation, Form 483s and equivalent forms from other Drug Regulatory Authorities) and correspondence, purged only of confidential information that is unrelated to the Product. LL shall permit Cadence's quality assurance representative to be present at the Facility during any such inspection by FDA or any other Drug Regulatory Authority that relates to the Product or LL's performance under this Agreement, provided, however, that Cadence shall only have access to or communicate with the inspectors during the facility inspection as permitted under the Quality Agreement. LL will also notify Cadence as soon as possible of LL's receipt of any other Form 483's or warning letters or any other significant regulatory action which LL's quality assurance group determines could impact the regulatory status of the Product. LL and Cadence will cooperate in resolving any concerns with any Drug Regulatory Authority, and Cadence may review LL's responses to any such reports and communications. LL will in its reasonable discretion incorporate into such responses any comments received from Cadence. LL will also inform Cadence of any action taken by any Drug Regulatory Authority against LL or any of its officers or employees which may be reasonably expected to adversely affect the Product or LL's ability to supply the Product hereunder within [\*\*\*].

(d) LL hereby grants Cadence the right to reference any drug master file regarding the Product or similar regulatory filing in the Territory that may now exist, or that may exist at any time during the Supply Term or any extension thereof, in any and all regulatory or other filings made by or on behalf of Cadence, its Affiliates or sublicensees. Upon the request of Cadence, LL shall provide Cadence with a letter evidencing such right of reference.

#### ARTICLE 5

#### CONFIDENTIALITY

5.1 <u>Confidentiality</u>. 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 Section 5.2 and Section 5.3 of the IV APAP Agreement.

#### ARTICLE 6

#### INDEMNIFICATION

6.1 <u>By LL</u>. LL shall indemnify, defend and hold harmless Cadence, its Affiliates and its and their employees, subcontractors, agents, officers and directors (each, a "<u>Cadence Party</u>") from and against all Losses by a Cadence Party that result from or arise out of any Claim against

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a Cadence Party to the extent such Claims or Losses are alleged to be or are in fact caused by, or are alleged to or in fact arise from or are based on any breach by LL or an LL Party of this Agreement or the Quality Agreement; provided, however, that LL shall not be obligated to indemnify a Cadence Party under this Agreement for any Losses incurred by such Cadence Party to the extent attributable to (i) any breach of this Agreement or the Quality Agreement by Cadence or a Cadence Party or (ii) negligence, gross negligence or willful misconduct on the part of Cadence or a Cadence Party.

6.2 By Cadence. Cadence shall indemnify, defend and hold harmless LL, its Affiliates and its and their employees, subcontractors, agents, officers and directors (each, an "LL Party"), from and against all Losses, liabilities, damages, fees (including, until such time as Cadence assumes control of a given Claim, reasonable attorneys' fees and costs of litigation pertaining to such Claim), and expenses paid or payable by an LL Party to a Third Party that result from or arise out of any Claim against an LL Party to the extent such Claim or any losses, liabilities, damages or fees, cost and expenses in connection therewith is alleged to be or is in fact caused by, or is alleged to or in fact arises from or is based on (y) any handling, storage, consumption, administration, injection, infusion, ingestion or other use or misuse of or exposure to the Product after the placement thereof at the disposal of Cadence's carrier at the designated port of departure, or (z) Cadence's decision not to recall the Product per LL's recommendation, as set forth in Section 3.10 of this Agreement; *provided, however*, that Cadence shall not be obligated to indemnify a Cadence Party under this Agreement for any Losses incurred by such Cadence Party to the extent attributable to (i) any breach of this Agreement or the Quality Agreement by LL or an LL Party or (ii) negligence, gross negligence or willful misconduct on the part of LL or any LL Party; (C) any negligence, gross negligence or willful misconduct on the Specifications when placed at the disposal of Cadence's carrier in accordance with Section 3.4; (B) any breach of this Agreement or the Quality Agreement by LL or any LL Party; (C) any negligence, gross negligence or willful misconduct on the part of LL or any LL Party; (C) any negligence pursuant to Section 6.1.

6.3 <u>Conditions to Indemnification</u>. A Party seeking indemnification under this Article 6 (the "<u>Indemnified Party</u>") shall give prompt notice of the Claim to the other Party (the "<u>Indemnifying Party</u>") and, provided that the Indemnifying Party is not contesting the indemnity obligation, shall permit the Indemnifying Party to control and assume the defense of any litigation relating to such Claim and disposition of any such Claim unless the Indemnifying Party is also a party (or likely to be named a party) to the proceeding in which such Claim is made and the Indemnifying Party gives notice to the Indemnifying Party shall not be so entitled to assume the defense of the case. If the Indemnifying Party does assume the defense of any Claim or proceeding, it (i) shall act diligently and in good faith with respect to all matters relating to the settlement or disposition of any Claim as the settlement or disposition relates to Parties being indemnified under this Article 6, (ii) shall cause such defense to be conducted by counsel reasonably acceptable to the Indemnified Party, or (iii) shall not settle or otherwise resolve any Claim without prior notice to the Indemnified Party and the consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed) if such settlement involves anything other than the payment of money by the Indemnifying Party. The Indemnified Party shall cooperate with the Indemnifying Party.

Party in its defense of any Claim for which the Indemnifying Party has assumed the defense in accordance with this Section 6.3, and shall have the right (at its own expense) to be present in person or through counsel at all legal proceedings giving rise to the right of indemnification.

6.4 Limitation of Liability. IN NO EVENT SHALL EITHER PARTY (OR ANY OF ITS AFFILIATES OR SUBCONTRACTORS) BE LIABLE TO THE OTHER PARTY FOR, NOR SHALL ANY INDEMNIFIED PARTY HAVE THE RIGHT TO RECOVER, ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES (INCLUDING LOST PROFITS OR DAMAGES FOR LOST OPPORTUNITIES), WHETHER IN CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE (WHETHER IN ANY CLAIM FOR INDEMNIFICATION PURSUANT TO THIS ARTICLE 6 OR OTHERWISE), ARISING (x) OUT OF THE MANUFACTURE, USE OR SALE OF ANY PRODUCT SOLD HEREUNDER OR (y) OUT OF ANY BREACH OF OR FAILURE TO PERFORM ANY OF THE PROVISIONS OF THIS AGREEMENT OR (z) ANY REPRESENTATION OR WARRANTY CONTAINED IN OR MADE PURSUANT TO THIS AGREEMENT, EXCEPT THAT SUCH LIMITATION SHALL NOT APPLY TO PUNITIVE OR CONSEQUENTIAL DAMAGES PAID OR PAYABLE TO A THIRD PARTY BY AN INDEMNIFIED PARTY FOR WHICH THE INDEMNIFIED PARTY IS ENTITLED TO INDEMNIFICATION HEREUNDER.

#### ARTICLE 7

#### DISPUTE RESOLUTION

7.1 <u>Dispute Resolution</u>. The Parties agree to attempt to resolve any dispute, difference or question arising between the Parties or any of their Affiliates or Indemnified Parties in connection with this Agreement or the Quality Agreement, the formation, interpretation, construction thereof or the rights, duties or liabilities of any Party or any of its Affiliates (a "<u>Dispute</u>") through good faith negotiations between the Parties in accordance with this Section 7.1 The disputing party shall provide notice of the existence and circumstances surrounding the Dispute to the other Party, in accordance with Section 9.1 of this Agreement. Within [\*\*\*] after the receipt by the non-disputing Party of any such notice, the respective officers designated below or such other officers as the Parties may designate in writing from time to time, shall meet in person to attempt to resolve the Dispute. The designated officers are as follows:

For LL: Glenn Peace General Manager

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For Cadence:

Scott A. Byrd, Chief Commercial Officer

If such dispute is not solved by the end of a [\*\*\*] period commencing upon the date on which the notice was received by the non-disputing Party, the Parties shall refer the matter to binding arbitration, as set forth in Section 7.2, below.

7.2 Arbitration. Except as otherwise provided in this Agreement, any Dispute, not resolved through good faith negotiations as set forth in Section 7.1 shall be resolved by binding arbitration in accordance with this Section 7.2. Any Party or any such Affiliate or Indemnified Party may require resolution of any such Dispute by arbitration hereunder by sending a written notice to the other Party demanding arbitration of the Dispute (the "Demand"). In that event, the Dispute shall be finally resolved by arbitration in accordance with the United States Arbitration Act and the Commercial Arbitration Rules of the American Arbitration Association. The venue for the arbitration shall be New York, New York. The arbitration shall be conducted in the English language before a panel of three (3) arbitrators. Each Party shall name one arbitrator, and the two so named shall name the third arbitrator, who shall act as chairman. If the two party arbitrators cannot agree on a third arbitrator within [\*\*\*] after the Demand, then at the request of either Party the President of the Association of the Bar of the City of New York shall appoint the third arbitrator. The arbitrators shall promptly meet, fix the time, date and place of the hearing and notify the Parties. All documents, exhibits, testimony or other information that is not in the English language shall be translated into the English language at the expense of the Party proffering the evidence requiring translation. The decision of the arbitrators may (depending on the equities of the case) include an award of legal fees, costs of arbitration and interest. The panel of arbitrators shall promptly transmit an executed copy of its decision to the Parties. The decision of the arbitrators shall be final, binding and conclusive upon the Parties. Judgment on the award rendered by the arbitrators may be entered in any court having jurisdiction thereof. Each Party retains the right to seek from a court any interim or provisional relief that may be necessary to protect the rights or property of that Party as permitted by Section 9.3 hereof pending the establishment of the arbitrators' determination of the merits of the controversy, and any such action shall not be deemed incompatible with this Agreement to arbitrate or a waiver of the right to arbitration. The obligations of the Parties under this Section are specifically enforceable and shall survive any termination of this Agreement. Unless the decision of the arbitrators provides otherwise, the Parties shall bear their own costs in preparing for the arbitration and the costs of the arbitrators shall be equally divided between the Parties.

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#### ARTICLE 8

#### TERM; TERMINATION

#### 8.1 Term; Termination.

(a) This Agreement shall commence on the Effective Date and shall continue for the Supply Term unless earlier terminated pursuant to this Section 8.1, or unless otherwise extended by written agreement of the Parties.

(b) This Agreement shall terminate upon the occurrence of any of the following events:

(i) the written consent of each of LL and Cadence to terminate this Agreement;

(ii) either Party's notice of its intent to terminate this Agreement for its convenience (without cause and without penalty) following eighteen (18) months' prior written notice;

(iii) the termination of the IV APAP Agreement; or

(iv) the dissolution or termination of Cadence, other than in connection with or following an assignment of this Agreement in accordance with Section 9.7.

(c) Either Party may, by written notice to the other Party, terminate this Agreement upon the occurrence of any of the following events:

(i) upon sixty (60) days' prior written notice in the event of a material breach of this Agreement by the other Party, which remains uncured by such other Party by the end of such sixty (60) day period; or

(ii) effective upon written notice to the other Party, if the other Party becomes insolvent or admits in writing its inability to pay its debts as they become due, files a petition for bankruptcy, makes an assignment for the benefit of its creditors or has a receiver, trustee or other court officer appointed for its properties or assets.

8.2 <u>Consequences of Termination</u>. Termination of this Agreement pursuant to this Article 8 shall be without prejudice to any rights which shall have accrued to the benefit of any Party prior to such termination. Such termination shall not relieve any Party from its obligations which are expressly indicated to survive the termination of this Agreement. All of the Parties' rights and obligations under the immediately proceeding sentence and under Sections 3.6, 3.7, 3.10, 3.11, 4.1, 4.2(c), 4.2(d) and 8.2 and Articles 5, 6, 7 and 9 hereof shall survive such termination for the applicable period.

(a) In the event of the termination of this Agreement by Cadence for its convenience under Section 8.1(b)(ii), or by BMS under Section 8.1(c)(i), Cadence will reimburse LL and its Affiliates for the cost of: (i) any Product ordered under any Firm Order and received by Cadence; and (ii) any inventory of Materials purchased by LL in order to produce the Product in accordance with any forecasts and vendor lead times to the extent that (A) such Materials are specific to the Product, and (B) LL and its Affiliate that holds such inventory are unable reasonably to utilize such inventory for other customers or for itself or any other LL Affiliate. Upon Cadence's request, LL shall deliver any such inventory of Materials to Cadence. Additionally, Cadence's Minimum Purchase Requirement for the Contract Year during which the effective date of any such termination occurs (i.e., 18 months after the notice of termination under Section 8.1(b)(ii)) shall be reduced proportionally, and Cadence shall not be obligated to purchase the Minimum Purchase Requirement for any subsequent Contract Year.

(b) In the event of the termination of this Agreement for any reason other than by Cadence for its convenience under Section 8.1(b)(ii) and by BMS under Section 8.1(c)(i), (i) Cadence shall not be required to reimburse LL or its Affiliates for the cost of any inventory of Materials purchased by LL in order to produce the Product, and (ii) Cadence shall have no obligation to purchase the Minimum Purchase Requirement for the Contract Year during which the effective date of any such termination occurs, or for any subsequent Contract Year.

#### ARTICLE 9

#### MISCELLANEOUS

9.1 Notices. All notices, consents, requests, demands and other communications required or permitted under this Agreement: (a) shall be in writing in the English language; (b) shall be sent by messenger, a reliable express delivery service or facsimile (with a copy sent by one of the foregoing means), charges prepaid as applicable, to the appropriate address(es) or number(s) set forth below; and (c) shall be deemed to have been given on the date of receipt by the addressee (or, if the date of receipt is not a Business Day, on the first Business Day after the date of receipt), as evidenced by (i) a receipt executed by the addressee (or a responsible person in his or her office), the records of the Person delivering such communication or a notice to the effect that such addressee refused to claim or accept such communication, if sent by messenger or express delivery service, or (ii) a receipt generated by the sender's fax machine showing that such communication was sent to the appropriate number on a specified date, if sent by facsimile. All such communications shall be sent to the following addresses or numbers, or to such other addresses or numbers as any Party may inform the others by giving five Business Days' prior notice:

If to Cadence: With a copy to: Cadence Pharmaceuticals, Inc. Cadence Pharmaceuticals, Inc. 12481 High Bluff Drive, Suite 200 12481 High Bluff Drive, Suite 200 San Diego, CA 92130 San Diego, CA 92130 Attn: Chief Commercial Officer Attn: Legal Department Fax No.: [\*\*\*] Fax No.: [\*\*\*] If to LL: With a copy to: Lawrence Laboratories Bristol-Myers Squibb Company Unit 12 Distribution Centre 1 Squibb Drive Shannon Industrial Estate New Brunswick, NJ County Clare Attn: Senior Counsel Technical Operations Ireland Fax No.: [\*\*\*] Attn: General Manager Fax No.: [\*\*\*] If to BMS: With a copy to: Bristol-Myers Squibb Company Bristol-Myers Squibb Company 1 Squibb Drive 1 Squibb Drive New Brunswick, NJ New Brunswick, NJ Attn: Director, Contract Manufacturing Attn: Assistant General Counsel Fax No.: [\*\*\*] Fax No.: [\*\*\*]

9.2 <u>Governing Law</u>. This Agreement is a contract under the laws of the State of New York and for all purposes shall be governed by, and construed and enforced in accordance with, the laws of said State, without giving effect to any conflict of law rules.

9.3 Equitable Relief. The Parties acknowledge and agree that each would be irreparably damaged in the event that any provision of this Agreement is not performed by the other in accordance with its specific terms or is otherwise breached. Accordingly, it is agreed that each Party is entitled to seek an injunction or injunctions to prevent breaches of this Agreement by the other and shall have the right to seek to specifically enforce this Agreement and the terms and provisions hereof against the other without the posting of any bond or other security, in addition to any other remedy to which such aggrieved Party may be entitled at law or in equity; provided, however, that the powers of the arbitrators under Section 7.2 shall be limited to enforcing the obligations provided for in this Agreement as drafted.

<sup>\*\*\*</sup> 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.

9.4 <u>Headings</u>. All titles or captions contained in this Agreement are for convenience of reference only and shall not limit or affect in any way the meaning or interpretation of this Agreement.

9.5 <u>No Third Party Beneficiaries</u>. This Agreement shall be binding upon, and inure solely to the benefit of, the Parties and their permitted assigns, and nothing herein, express or implied, is intended to, or shall confer upon, any other Person any legal or equitable right, benefit or remedy of any nature whatsoever.

9.6 Severability. If any term or other provision of this Agreement is held to be invalid, illegal or incapable of being enforced by any Applicable Law or public policy, all other terms and provisions of this Agreement shall nevertheless remain in full force and effect so long as the economic or legal substance of the transactions contemplated hereby is not affected in any manner materially adverse to any Party. Upon such determination that any term or other provision is invalid, illegal or incapable of being enforced, the Parties shall negotiate in good faith to modify this Agreement so as to effect the original intent of the Parties as closely as possible in an acceptable manner in order that the transactions contemplated hereby are consummated as originally contemplated to the greatest extent possible.

#### 9.7 Assignment and Subcontracting.

(a) Except as set forth below in this Section 9.7 neither this Agreement, nor any right, interest or obligation hereunder, may be assigned, pledged or otherwise transferred by any Party, whether by operation of law or otherwise, without the prior consent of the other Party, except that either Party may assign any of its rights or delegate any of its obligations hereunder to any of its Affiliates, <u>provided</u>, that (i) the assigning Party shall provide the other Party with written notice of any such assignment or delegation, (ii) the assigning Party shall unconditionally guarantee the full and timely performance by its Affiliate of such Party's obligations under this Agreement, which guarantee shall be a continuing guaranty and remain in full force and effect for so long as there shall remain any obligations (including, without limitation, any indemnification obligations) or any representations or warranties of the assigning Party under this Agreement; and (iii) such Affiliate shall have first agreed in writing to be bound by the terms of this Agreement in connection with such delegated obligations. Cadence acknowledges that LL will delegate the manufacturing of the Product to its Affiliate, Bristol-Myers Squibb S.R.L., in Italy and that delegation to such Affiliate shall not require any further notice to Cadence.

(b) Either Party may assign or transfer all of its rights and obligations hereunder without the prior consent of the other Party to a successor in interest by reason of merger, consolidation or sale of substantially all of the assets of the assigning Party (and so long as such assignment or transfer includes, without limitation, all Approvals, all manufacturing assets relating to the IV APAP Agreement, and all rights and obligations under the IV APAP Agreement); provided, that such successor in interest shall have agreed prior to such assignment or transfer to be bound by the terms of this Agreement in a writing provided to the other Party.

(c) LL may not subcontract any or all of its obligations under this Agreement to any Third Party without the prior written consent of Cadence in its sole and absolute discretion.

(d) Not withstanding anything to the contrary herein, any assignment, delegation or subcontracting by a Party of any of its rights or obligations under this Agreement shall not relieve such Party from any of its obligations hereunder.

(e) Any assignment or transfer in violation of the foregoing shall be null and void and wholly invalid, the assignee or transferee in any such assignment or transfer shall acquire no rights whatsoever, and the non-assigning non-transferring Party shall not be required to recognize, such assignment or transfer.

(f) Subject to the foregoing, this Agreement shall inure to the benefit of and be binding on the Parties' successors and permitted assigns.

9.8 <u>Consents</u>. Any consent or approval to any act or matter required under this Agreement shall be in writing and shall apply only with respect to the particular act or matter to which such consent or approval is given, and shall not relieve any Party from the obligation to obtain the consent or approval, as applicable, wherever required under this Agreement to any other act or matter.

9.9 Entire Agreement. This Agreement contains the entire agreement of the Parties with respect to the subject matter of this Agreement and supersedes all prior written and oral agreements, and all contemporaneous oral agreements, relating to such subject matter. Notwithstanding the foregoing, nothing in this Agreement shall be deemed to modify, amend or waive any provision of the IV APAP Agreement.

9.10 Exhibits. The Exhibits attached to this Agreement are an integral part hereof and all references to this Agreement include such Exhibits.

9.11 <u>Waivers and Amendments</u>. No modification of or amendment to this Agreement shall be valid unless in a writing signed by all Parties referring specifically to this Agreement and stating the Parties' intention to modify or amend the same. Any waiver of any term or condition of this Agreement shall be in a writing signed by the Party sought to be charged with such waiver referring specifically to the term or condition to be waived, and no such waiver shall be deemed to constitute the waiver of any other breach of the same or of any other provision hereof.

9.12 No Partnership or Joint Venture. This Agreement is not intended to create, and nothing contained herein shall be construed to create, an association, joint venture, trust or partnership, or to impose a trust or partnership covenant, obligation or liability on or with regard to the other Party. Each Party shall be severally responsible for its own covenants, obligations and liabilities as herein provided. No Party shall be under the control of, or shall be deemed to control any other Party; no Party is the legal representative, agent, joint venturer or employee of the other Party with respect to this Agreement for any purpose whatsoever; no Party shall have the right or power to bind the other Party; and no Party has the right or authority to assume or create any obligations of any kind or to make any representation or warranty on behalf of any other Party, whether express or implied, or to bind any other Party in any respect whatsoever. The provisions of this Agreement are intended only for the regulation of relations between the Parties.

9.13 <u>Absence of Presumption</u>. With regard to each and every term and condition of this Agreement and any and all agreements and instruments subject to the terms hereof, the Parties hereto understand and agree that the same have or has been mutually negotiated, prepared and drafted, and if at any time the Parties hereto desire or are required to interpret or construe any such term or condition or any agreement or instrument subject hereto, no consideration shall be given to the issue of which Party hereto actually prepared, drafted or requested any term or condition of this Agreement or any agreement or instrument subject hereto.

9.14 <u>Counterparts; Facsimile Execution</u>. This Agreement may be executed in any number of counterparts, and by each of the Parties on separate counterparts, each of which, when so executed, shall be deemed an original, but all of which shall constitute but one and the same instrument. Delivery of an executed counterpart of this Agreement by facsimile shall be equally as effective as delivery of a manually executed counterpart of this Agreement.

[Remainder of page intentionally left blank.]

#### SIGNATURE PAGE TO SUPPLY AGREEMENT

IN WITNESS WHEREOF, the Parties have duly executed this Agreement as of the day and year first above written.

#### LAWRENCE LABORATORIES

- By: /s/ Glenn Peace
- Name: Glenn Peace
- Title: General Manager

#### CADENCE PHARMACEUTICALS, INC.

- By: /s/ Theodore R. Schroeder
- Name: Theodore R. Schroeder

Title: President and CEO

# EXHIBIT A

# **SPECIFICATIONS**

#### Cadence Pharmaceuticals, Inc.

Acetaminophen, Injection for Intravenous Use

# [\*\*\*]

# Confidential/Trade Secret/Proprietary Information of Cadence Pharmaceuticals, Inc.

\*\*\* 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 B

# **INITIAL FORECAST**

[\*\*\*]

\*\*\* 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.