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): October 9, 2019

CATALYST BIOSCIENCES, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	000-51173	56-2020050
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

611 Gateway Blvd, Suite 710, South San Francisco, CA 94080
(Address of principal executive offices)

(650) 871-0761
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report.)

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

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

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

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

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	**CBIO**	**Nasdaq**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.01. Entry into a Material Definitive Agreement.

On October 9, 2019, Catalyst Biosciences, Inc., (the "Company") and Catalent Indiana, LLC., ("Catalent") executed a Clinical Supply Agreement (the "Clinical Supply Agreement"), effective as of October 4, 2019. The Clinical Supply Agreement provides the general terms and conditions pursuant to which Catalent, using Company-supplied materials and components, will produce formulated drug products including the related development and regulatory services (the "Products") for the Company's development and/or clinical use.

The Products to be produced by Catalent under the Clinical Supply Agreement shall be set forth in one or more project plans entered into by the parties from time to time. Each project plan shall be incorporated by reference into the Clinical Supply Agreement and provide the parameters for each project.

The Company will own, and Catalent assigns to the Company, the intellectual property that is specifically related to the Products including the Products' composition and use, and Catalent will own, and the Company assigns to Catalent, the intellectual property that result from Catalent's performance of its services under the Clinical Supply Agreement.

The initial term of the Clinical Supply Agreement is three years, although the term may be extended for successive twelve-month periods, unless either party gives the other party written notice of its intent not to extend the term at least ninety (90) days prior to the expiration of the initial term or the then-current extension. Either party may terminate the Clinical Supply Agreement in its entirety upon written notice of a material uncured breach or upon the other party's bankruptcy, and the Company may terminate the Clinical Supply Agreement for its convenience upon thirty (30) days prior written notice. In addition, each party may terminate the Clinical Supply Agreement in the event that the other party fails to perform its obligations under the Clinical Supply Agreement for reasons beyond the reasonable control of such party, such as technical or scientific reasons. If the Company cancels or reschedules a project plan or purchase order outside the parameters set in the Clinical Supply Agreement, the Company would be obligated to pay for a portion of Catalent's costs less certain fees that Catalent is able to mitigate.

The foregoing description of the Clinical Supply Agreement is not complete and is qualified in its entirety by reference to the full text of the Clinical Supply Agreement which is filed as Exhibit 10.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
10.1*	Clinical Supply Agreement, effective as of October 4, 2019, by and between Catalyst Biosciences, Inc. and Catalent Indiana, LLC.

* Confidential portions of this exhibit were redacted pursuant to Item 601(b)(10) of Regulation S-K and Catalyst Biosciences, Inc. agrees to furnish supplementally to the U.S. Securities and Exchange Commission a copy of any omitted schedule and/or exhibit upon request. The confidential portions of this exhibit were omitted by means of marking such portions with asterisks because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

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.

CATALYST BIOSCIENCES, INC.

Date: October 15, 2019

By: /s/ Nassim Usman

Nassim Usman, Ph.D.
President and Chief Executive Officer

Certain information identified by bracketed asterisks ([* * *]) has been omitted from this exhibit because it is both not material and would be competitively harmful if publicly disclosed.

CLINICAL SUPPLY AGREEMENT

DRUG PRODUCT

THIS CLINICAL SUPPLY AGREEMENT (this "**Agreement**") is entered into and effective this 4th day of October 2019 ("**Effective Date**") by and between **Catalent Indiana, LLC**, a Delaware limited liability company with offices 1300 South Patterson Drive, Bloomington, IN 47403 ("**Catalent**") and **Catalyst Biosciences, Inc.** ("**Client**"), a Delaware corporation with offices at 611 Gateway Boulevard, Suite 710, South San Francisco, CA 94080. In this Agreement, Catalent and Client each may be referred to individually as a "**Party**" and together as "**Parties**."

RECITALS

WHEREAS, Catalent is a leading provider of advanced technologies, and development, manufacturing and packaging services, for pharmaceutical, biotechnology and consumer healthcare companies;

WHEREAS, Client develops pharmaceutical products; and

WHEREAS, Client desires to have Catalent provide the Services (as defined below) set forth in this Agreement and any Project Plan, and Catalent desires to provide such Services to Client through certain of its locations (see definition of Facility below), all pursuant to the terms and conditions in this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, the Parties agree as follows:

AGREEMENT

1. Definitions. For purposes of this Agreement, the following terms will have the meanings set forth below:

1.1 "**Affiliate**" with respect to Client, means Catalyst Biosciences, Inc. and any corporation, firm, partnership or other entity controlled by it; and with respect to Catalent, means Catalent, Inc. and any corporation, firm, partnership or other entity controlled by it. For the purposes of this definition, "control" means the ownership of at least 50% of the voting share capital of an entity or any other comparable equity or ownership interest.

1.2 "**ANDA**" means an Abbreviated New Drug Application.

1.3 "**Applicable Laws**" with respect to Client, means all laws, ordinances, rules and regulations, as amended from time to time, of each jurisdiction in which Bulk Drug Substance or Product is produced, marketed, distributed, used or sold by or on behalf of Client; and with respect to Catalent, means all laws, ordinances, rules and regulations, as amended from time to time, of the jurisdiction in which Catalent performs Services; provided that CGMP shall not constitute Applicable Laws except to the extent expressly stated in the applicable Project Plan.

1.4 "**Batch**" means a specific quantity of a Product comprising a number of Units mutually agreed upon between Client and Catalent, and that: (a) is intended to have uniform character and quality within specified limits; and (b) is Produced according to a single manufacturing order during the same cycle of Production.

1.5 "**Batch Record Package**" has the meaning stated in the Quality Agreement.

1.6 "**BLA**" means a Biologic Licensing Application.

1.7 "**Bulk Drug Substance**" means the bulk form of the active ingredient identified in the Project Plan that is used in the Production of Product.

1.8 "**Certificate of Analysis**" means a document listing all test results for a Product, Raw Material, or Component compared to the respective Specifications.

1.9 "**CGMP**" means those current practices, as amended from time to time, related to the manufacture of biopharmaceuticals and pharmaceuticals as set forth in the FDCA and such standards of good manufacturing practice as are required by the FDA or other Regulatory Authorities (as defined herein), as agreed in the Project Plan and as may be set forth in the United States Code of Federal Regulations (Title 21, Parts 210-211).

1.10 "**Client Confidential Information**" means: (a) all Confidential Information owned or controlled by Client that is disclosed to Catalent under this Agreement; and (b) all Information concerning Product Specifications, Client Intellectual Property Rights, Client Materials, Component Specifications, Master Batch Records, and Product Inventions.

1.11 "**Client Intellectual Property Rights**" means: (a) all patent and other intellectual property rights owned or controlled by Client as of the Effective Date; and (b) all patent and other intellectual property rights developed, authored, conceived, or reduced to practice by or on behalf of Client not in connection with this Agreement.

1.12 "**Client Materials**" means the materials for use in the Production supplied by Client to Catalent, or that Catalent does not routinely stock and specially procures on behalf of Client as outlined in the executed Project Plan.

1.13 "**Client Trademarks**" means the proprietary mark(s) for Product owned or controlled by Client as identified in a Project Plan.

1.14 "**Component Specifications**" means the Specifications for the Components set forth in the Project Plan, including the testing (if any) to be performed for the Components, as set forth in the Project Plan.

1.15 "**Components**" means all primary product-contact components (such as vials, plungers, stoppers and syringes) or product-delivery devices (such as secondary devices or injectors) of the type required for Production. All Components will be specified and listed in the Project Plan and may be identified as either Components supplied by Client ("**Client-Supplied Components**") and/or Components supplied by Catalent ("**Catalent-Supplied Components**").

1.16 "**Confidential Information**" shall mean all information and materials acquired from the other Party or its Affiliates, employees, subcontractors, suppliers, agents, distributors, licensees or customers in connection with this Agreement, as well as all other information and materials included in the Client Confidential Information.

1.17 "**Catalent Intellectual Property Rights**" means: (a) all patent and any other intellectual property rights owned or controlled by Catalent as of the Effective Date; and (b) those intellectual property rights that are developed, authored, conceived, or reduced to practice by or on behalf of Catalent not in connection with this Agreement.

1.18 "**Catalent Project Product Code**" means the identifying alphanumeric code established by Catalent to identify the Product as set forth in the Project Plan.

1.19 "**Claim**" means any claim, demand, suit, action, or proceeding.

1.20 "**Damages**" means any and all costs, losses, liabilities, fines, penalties, costs and expenses, court costs, and fees and disbursements of counsel, consultants and expert witnesses incurred by a Party hereto (including interest which may be imposed in connection therewith).

1.21 "**Dedicated Equipment**" means the equipment, if any, identified on a Project Plan as "Dedicated Equipment" that is purchased or otherwise provided by Catalent or Client and exclusively dedicated to use by Catalent in the provision of the Services.

1.22 "**Development/Engineering Batch**" shall have the meaning set forth in Section 3.3.

1.23 "**EMA**" means the European Medicines Agency and any successor agency having substantially the same functions.

1.24 "**Facility**" means the Catalent manufacturing facility located at 1300 South Patterson Drive, Bloomington, Indiana 47403.

1.25 "**FDA**" means the United States Food and Drug Administration and any successor agency or entity that may be established hereafter.

1.26 "**FDCA**" means the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 301 et seq.).

1.27 "**Firm Order**" means any of the following, each of which shall constitute a commitment by Client to purchase Product: (i) a Project Plan duly executed by the Parties which contains a binding order for the Product; or (ii) an accepted and confirmed purchase order that is subject to the terms and conditions of this Agreement.

1.28 "**Force Majeure**" means causes beyond the reasonable control of a Party including, without limitation, acts of God (including but not limited to earthquake, tornado or hurricane), laws, regulations or actions of any government or agency thereof, war, terrorism, civil commotion, damage to or destruction of production facilities or materials, scientific or technical events, labor disturbances (whether or not any such labor disturbance is within the power of the affected Party to settle) and pandemic or epidemic events.

1.29 "**Indemnitee**" has the meaning stated in Section 7.3 ("Procedure for Indemnification").

1.30 "**Indemnitor**" has the meaning stated in Section 7.3 ("Procedure for Indemnification").

1.31 "**Initial Term**" has the meaning stated in Section 10.1 ("Term").

1.32 "**Inventions**" means all innovations, inventions, improvements, original works of authorship, developments, concepts, know-how and/or trade secrets, whether or not patentable, resulting from the performance of the Services.

1.33 "**Master Batch Record**" means, with respect to each Presentation of Product to be Produced hereunder, a formal set of instructions for the Production of each Presentation of such Product.

1.34 "**NDA**" means a New Drug Application.

1.35 "**Nonconforming Product**" has the meaning stated in Section 4.1 ("Product Conformity").

1.36 "**Non-Defaulting Party**" has the meaning stated in Section 10.2 ("Termination for Breach").

1.37 "**Party**" or "**Parties**" has the meaning stated in the opening paragraph.

1.38 "**Permitted Subcontractor**" has the meaning stated in Section 12.12 ("Subcontracting").

1.39 "**Person**" means a natural person, a corporation, a partnership, a trust, a joint venture, a limited liability company, any governmental authority or any other entity or organization.

1.40 "**Presentation**" means the specific formula and Components used for a Product.

1.41 "**Price**" has the meaning stated in Section 5.1 ("Product Price").

1.42 "**Process**" means the formulation, filling, inspecting, labeling, packaging and testing of the Product using the Product Specifications in accordance with the Master Batch Record, including any improvements thereto from time to time made as a direct result of the Services during the Term of the Agreement.

1.43 "**Process Consumables**" shall mean materials used as an aid in the Production of Product that do not become part of the finished Product including but not limited to filters, tubing, Product contact disposables, containers, and bags.

1.44 "**Product Liability Claims**" means, with respect to any Product, a Claim of a third party that arises as a result of the use of such Product that results in personal injury or death.

1.45 "**Produce**" or "**Production**" means the verb form of the term Process.

1.46 "**Product**" means the formulated Bulk Drug Substance in syringes, cartridges, and/or vials packaged as specified in the applicable Project Plan(s).

1.47 "**Product Availability Date**" means the date that Product is made available to Client or its designated carrier in accordance with the Delivery Terms.

1.48 "**Product Invention**" means any Invention that specifically relates to the Product (including relating to the Components or to the composition or utility of the Bulk Drug Substance or the Product) and that is developed, conceived, or reduced to practice by or on behalf of Client or Catalent in the performance of the Services. For the avoidance of doubt, a Product Invention shall include Inventions made by or on behalf of Catalent, by or on behalf of Client, or jointly by or on behalf of Catalent and Client.

1.49 "**Product Requirements**" has the meaning stated in Section 4.1 ("Product Conformity").

1.50 "**Product Specifications**" means, with respect to each Product, the Specifications for the Product, and/or the stability program that are set forth in the Client-specific standard operating procedures and the Master Batch Records. The Product Specifications include all tests that Catalent is required to conduct or cause to be conducted as specified in the Project Plan. The Product Specifications may be modified from time to time only by a written agreement signed by Client and Catalent.

1.51 "**Project Invention**" means any Invention developed, conceived, or reduced to practice during the Term in the course of, and as a direct result of, performing the Services, excluding Product Inventions. For the avoidance of doubt, a Project Invention shall include Inventions made solely by or on behalf of Catalent, by or on behalf of Client or jointly by or behalf of Catalent and Client.

1.52 "**Project Plan**" means all document(s) labeled "Project Plan" that refer to this Agreement, and that are signed by authorized representatives of both Parties setting forth the proposed course of action for the Production of Product and/or performance of Services at a specified Facility. A Project Plan may include, without limitation, a description of the Product, Components, Regulatory Authorities and the countries where such Product will be used or sold, Presentations, Bulk Drug Substance, pricing for Product(s) Produced and Services provided under this Agreement as set forth in Section 3.5 ("Project Plan"), and any applicable reservation fee necessary to reserve a manufacturing suite for CGMP services.

1.53 "**Quality Agreement**" means the Quality Agreement applicable to the Services being performed by Catalent.

1.54 "**Quality Disposition**" means disposition of Product by Catalent's Quality Assurance department following Catalent Quality review of executed Batch documentation.

1.55 "**Raw Materials**" means the materials used in the Production of the Product that may become part of the finished Product such as Bulk Drug Substance, excipients, media components, and buffer components.

1.56 "**Regulatory Approval**" means all authorizations, approvals, licenses, and registrations issued by or otherwise required from the appropriate Regulatory Authority necessary for the Production, distribution, use or commercial sale in a jurisdiction.

1.57 "**Regulatory Authority**" means any national, state, provincial, or local or any foreign or supranational government, governmental, regulatory or administrative authority, agency or commission of any court, tribunal or judicial or arbitral body.

1.58 "**Safety Data Sheet**" or "**SDS**" is a document that contains information on the potential hazards (health, fire, reactivity and environmental) and how to work safely with the chemical product. It also contains information on the use, storage, handling and emergency procedures related to the hazards of the material.

1.59 "**Services**" means all or any part of the activities, including the Production of Product, development services, and/or regulatory services for Client, to be performed by Catalent (and any Permitted Subcontractor) pursuant to this Agreement as further described in the executed Project Plan.

1.60 "**Specification(s**)" means the tests, analytical procedures, and appropriate acceptance criteria that are numerical limits or ranges that establish a set of criteria to which a raw material, component, drug substance or drug product must conform to be acceptable for its intended use.

1.61 "**Term**" has the meaning stated in Section 10.1 ("Term").

1.62 "**Testing Laboratories**" means any third party instructed by Catalent to carry out tests on the Bulk Drug Substance, and/or the Product.

1.63 "**Tests**" means the tests to be carried out on the Product (or samples thereof) immediately following pick-up of the Product (or samples thereof) by Client, as stated in the Project Plan.

1.64 "**Testing Standards and Procedures**" means, with respect to each Product Produced hereunder, the written standards and procedures for evaluating compliance with the applicable Product Specifications, as mutually agreed upon in writing by Client and Catalent and incorporated in the applicable Project Plan.

1.65 "**Unit**" means an individually packaged dosage form of a Product, including by way of example only, a vial or prefilled syringe, as specified in the applicable Project Plan.

1.66 "**United States**" means the fifty (50) states, the District of Columbia and all of the territories of the United States of America.

2. Sourcing of Materials and Components.

2.1. **Client-Supplied Raw Materials and Components Delivery**. Client, at Client's sole expense, shall deliver or cause to be delivered to the Facility: (a) a reasonably sufficient amount of Client-supplied Raw Materials, and Certificates of Analyses, for Production of the Product in accordance with the applicable Project Plan; and (b) all Client-Supplied Components listed in the applicable Project Plan, all of which shall be delivered to Catalent at the Facility at least [***] days in advance of the date set forth in the applicable Project Plan for commencement of Production of such Product. Except as may specifically be set forth in the Project Plan, on receipt of the Client-supplied Raw Materials and Client-Supplied Components as set forth above, Catalent's sole obligation with respect to evaluation of the Client-supplied Raw Materials and Client-Supplied Components shall be to conduct identification testing and to review the accompanying Certificate of Analysis to confirm that the Client-supplied Raw Materials and Client-Supplied Components (if applicable) conform with the Product Specifications and Component Specifications, respectively. Catalent shall use [***] efforts to minimize loss of the Bulk Drug Substances at all times while in Catalent's possession and control, including during the course of Producing the Product, and to otherwise maximize the yield of the Product during Production.

2.2. **Safety Data Sheet**. Client shall provide to Catalent a Safety Data Sheet for all Client materials (including, if applicable, Bulk Drug Substance) and for each Product. Catalent shall notify Client of any unusual adverse health or environmental occurrence relating to the Product, including but not limited to any claim or complaint by any Catalent employee or third party that the

operations of Catalent pursuant to this Agreement have resulted in any adverse health or safety effect on an employee or third party. Each Party agrees to advise the other Party immediately of any safety or toxicity problems of which it becomes aware regarding the Product and/or the Client Materials.

2.3. **License Grant**. Subject to the terms and conditions of this Agreement, Client hereby grants to Catalent a non-exclusive, non-sublicensable (except to Permitted Subcontractors), non-transferable license during the Term (except as otherwise set out in this Section 2.3) under Client's intellectual property rights in the Client Confidential Information, the Client Intellectual Property Rights, the Product Inventions, and the Client Materials solely for the purpose of performing Catalent's obligations under this Agreement. The foregoing license shall extend beyond termination of this Agreement solely as necessary to complete the Production of outstanding Firm Orders.

2.4. **Catalent Obligations Relating to Client Materials**. Catalent shall:

2.4.1 at all times use [***] efforts to keep the Client Materials secure and safe from loss or damage;

2.4.2 at all times store and handle the Client Materials under qualified conditions in a secured storage location in accordance with Client's handling and storage instructions and CGMP;

2.4.3 use the Client Materials solely for the purpose of performing the Services; and

2.4.4 not transfer to a third party any part of the Client Materials or the Product, except to Permitted Subcontractors as may be permitted in the Project Plan.

2.5. **Ownership and Risk of Loss**. Client shall own and continue to own all right, title and interest in and to Client Materials. Client assumes any and all risk of loss, damage, theft or destruction of Client Materials and Product while the Client Materials and Product are in Catalent's possession, on Catalent's premises, or while between Catalent Facilities; [***] that [***] hereby [***], and [***] be [***], for [***], or [***] of [***] and [***] from [***], all [***] to the [***] set forth in [***]. Upon termination or expiration of this Agreement, Client shall promptly notify Catalent whether Client shall either: (a) reclaim possession of Client Materials and Product; or (b) request destruction of Client Materials and Product by Catalent, each at Client's sole expense. If Client fails to provide Catalent such notice within [***] days following expiration or termination of this Agreement, Catalent shall destroy Client Materials and Product at Client's sole expense. Catalent shall invoice Client (and Client shall pay) for all costs incurred as a result of the return or destruction of the Client Materials and Product.

2.6. **Vendor and Supplier Audit and Certification**. Catalent shall certify and audit all Product-related vendors and suppliers of Catalent-Supplied Components, Raw Materials, and Process Consumables at its sole expense unless the responsibility for such certifications and audits is specifically assumed by Client under the Project Plan. Client shall certify and audit all vendors and suppliers of Client-supplied Raw Materials and Client-Supplied Components unless the responsibility for such certification and audits is specifically assumed by Catalent under the Project Plan and Client shall pay for such audits as set forth therein.

2.7. **Client-Supplied Components**. Client shall supply to Catalent, or cause to be shipped to Catalent, all Client-Supplied Components at Client's expense.

2.8. **Catalent-Supplied Components**. Catalent will use [***] efforts to purchase the Catalent-Supplied Components in quantities sufficient to meet Client's Firm Orders for Product, including additional quantities as necessary for efficient supply chain management practices. Client shall reimburse Catalent for the Catalent-Supplied Components as set forth in the Project Plan. Stock materials will be invoiced upon consumption. Custom (or non-stock) materials purchased by Catalent for Client will be invoiced (and title shall transfer to Client) upon receipt of such non-stock materials by Catalent. Such materials shall be deemed Client Materials upon transfer of title to Client. Generation of invoices and payment for Catalent-Supplied Components shall be made in accordance with Section 5.3 ("Payment Terms") of this Agreement.

3. Purchase and Supply of Product.

3.1. **Agreement to Purchase and Supply**. Pursuant to the terms and conditions of this Agreement and the applicable Project Plan, Client shall purchase from Catalent, and Catalent shall perform the Services and/or Produce and deliver to Client, the Product.

3.2. **Performance**. Catalent shall diligently perform the Services and/or the Production as provided in the applicable Project Plan, including by meeting the schedule and Producing the Product in accordance with the Product Specifications and quantities provided in the applicable Project Plan and the approved purchase orders (unless such schedules are estimates, in which case Catalent will use [***] efforts to meet such schedules). Catalent shall Produce Product in accordance with CGMP, all Applicable Laws, and all requirements set forth by applicable Regulatory Authorities. Client acknowledges that the

Services to be performed pursuant to this Agreement and the Project Plan are developmental and that the Services may involve biological processes that are, by their nature, unpredictable, and Catalent does not guarantee to Client the achievement of a successful outcome. It shall not be considered a breach by Catalent of this Agreement or the applicable Project Plan if an objective of the applicable Project Plan is not achieved as long as Catalent has complied with its obligations set forth in this Agreement and in the applicable Project Plan. Notwithstanding Section 12.12, Catalent shall have the right to cause any of its Affiliates to perform any of its obligations pursuant to this Agreement, and Client shall accept such performance as if it were performance by Catalent. Catalent shall be responsible for the acts and omissions of its Affiliates in connection with the performance of Catalent's obligations under this Agreement as if such act or omissions were performed by Catalent.

3.3. **Development/Engineering Batch**. Except as otherwise agreed by the Parties in writing, the [***] of [***] by [***] shall be considered to be a "**Development/Engineering Batch**." Additionally, the [***] of the [***] Produced following: (a) a material change in Product Specifications; or (b) a change in scale of the manufacturing process to produce different quantities of Product shall be considered a Development/Engineering Batch.

3.4. **Reproduction, Rework or Reprocessing**. If, during the Production of any Batch of Product, any reprocessing, rework, or reproduction is required in order to meet the Product Specifications, upon Client's prior, written approval, Catalent shall conduct such reprocessing, rework, or reproduction in compliance with CGMPs and the BLA or NDA (as applicable). Catalent will notify Client if any reprocessing, rework, reproduction, or change is not covered by CGMPs, the NDA, or BLA. Approved reprocessing, rework, or reproduction shall be billed separately to Client at mutually agreed upon, commercially reasonable fees.

3.5. **Project Plan**.

3.5.1 **Project Plan**. For each Product to be Produced by Catalent hereunder, the Parties shall execute one or more written Project Plan(s) prior to commencement of any work or commitment by Catalent to purchase or supply any Services, Raw Materials or equipment, or reservation of production capacity or schedule slots. Catalent, or any of its Affiliates, may enter into one or more Project Plan(s) with Client under this Agreement, and such Affiliate shall assume the rights and obligations of Catalent under this Agreement for purposes of any applicable Project Plan(s). Each Project Plan

shall describe the Production with respect to the applicable Product, the budget for such Project Plan, and certain other relevant terms and conditions for performance of the Production by Catalent under this Agreement. In no event shall Catalent be required to schedule the Production of any Product until a Project Plan for such Product has been approved in writing by both Catalent and Client. Each agreed-upon Project Plan shall be incorporated herein by reference and shall constitute a Firm Order.

3.5.2 **Modification and Project Plan Scope Changes**. From time to time, but no less often than once per month, the Parties will meet to review and, if necessary, update, by mutual agreement, each Project Plan. In the event that the Parties agree to update, modify or expand the scope of a Project Plan, or to formally approve the accumulated minor project changes as set forth in the following Section, such amended Project Plan will become part of this Agreement in the manner stated in Section 3.5.1 ("Project Plan") upon execution of that Project Plan by authorized representatives of both Parties. No Project Plan may be modified, amended, or supplemented except by written agreement by the Parties.

3.5.3 **Minor Project Changes**. The Catalent project manager shall maintain an ongoing log which tracks all Client-requested or Catalent-requested minor changes to the activities and items contained in an executed Project Plan. All such minor changes must be approved in writing by the Client project manager and the Catalent project manager in order to take effect. Catalent is authorized to implement (and charge Client for) all such approved minor changes, provided that if the estimated total value of such tracked changes exceeds [***] percent of the total price of the Project Plan, then a formal Project Plan amendment must be prepared, agreed to, and executed as set forth in the previous Section.

3.6. **No Amendment of Agreement**. In the event that the terms of any Project Plan are inconsistent with the terms of this Agreement, this Agreement shall control, unless otherwise explicitly agreed to in writing by the Parties. No Project Plan shall be deemed to amend this Agreement. Upon execution of any Project Plan, such plan shall be deemed to be incorporated herein and by reference and made a part of this Agreement.

3.7. **Effect of Failure to Execute Plans or Addendum**. No Party will have any obligations with respect to a particular Product until the Parties execute a Project Plan with respect to that particular Product.

3.8. **Cancellation of Firm Order**. Client may cancel or delay any Firm Order [***] by providing [***] of the [***]; provided, however, that if [***] than [***] in [***] by [***], then [***]: (i) [***] for the [***] that [***] and has [***] or [***], if such [***] by [***] for the [***] and such [***] used [***]; and (ii) [***] and [***] by [***] up to the time of [***] of [***]. To the extent that such cancellation or delay causes Client to miss a Batch production slot ("**Missed Slot**"), Catalent will use [***] efforts to: (a) move the batch of another Catalent customer into such Missed Slot (subject to such customer's consent and provided that such movement does not cause a subsequent empty slot in Catalent's schedule within the following [***] calendar weeks); and (b) mitigate and otherwise minimize costs relating to such Missed Slot (including cancelling all revocable fees and expenses), and any fees due to Catalent under this Section 3.8 will be reduced by the sum of the fees paid for by such other customer for such batch.

3.9. **Storage**.

3.9.1 **Client-Supplied Component Storage**. Catalent shall store all Client-Supplied Components for the remainder of the calendar month in which Client-Supplied Components arrive at Catalent and for the [***] following calendar months, without charge. On the first day of each calendar month thereafter that the Client-Supplied Components are stored by Catalent, Catalent shall invoice Client (and Client shall pay) for a full month of storage for such Client-Supplied Components. In no event shall Catalent be required to store any such Client-Supplied Components for more than ninety (90) days without Catalent's consent.

3.9.2 **Product Storage**. During the Term, Catalent shall store Products using the Dedicated Equipment after Catalent Quality Disposition for the Products takes place. If the Dedicated Equipment fails, is full, or is not available, Catalent may make other arrangements for storage (as described in, and subject to, Section 3.9.3).

3.9.3 **Storage Pricing and Off-Site Storage**. Catalent shall be permitted to store Product and Client-Supplied Components in mutually acceptable off-site, third party storage facilities. The applicable Project Plan may include pricing for storage, and Client agrees to pay for such storage for as long as the Client-Supplied Components remain at Catalent's Facility or at a mutually acceptable off-site storage facility. Catalent shall be responsible for any such off-site storage. If the Project Plan does not set forth storage charges, storage shall be charged at Catalent's generally applicable storage rates that are in effect at the time the storage occurs.

3.9.4 **Default**. In the event of a default by Client with respect to payment of storage fees for the Client-Supplied Components that is not cured within [***] days of Catalent's written notice to Client of such default, then Catalent may at its sole discretion dispose of such items and invoice Client for all reasonable disposal costs incurred by Catalent and set-off any and all amounts due to Catalent from Client under this Agreement against any credits Client may hold with Catalent under this Agreement.

3.10. Changes in Manufacturing.

3.10.1 **Changes to Master Batch Records**. Catalent agrees to inform Client within [***] days of the result of any regulatory development that reasonably may materially affect the Production of the Product. Catalent shall notify Client of and require timely written approval from Client for changes to Master Batch Records and Product Specifications prior to the Production of subsequent Batches of Product. Within [***] days of learning from Catalent of such regulatory development, Client may either: (i) terminate this Agreement upon written notice to Catalent (in which case Client shall be liable for any unfilled Firm Orders as of the termination date in accordance with Section 3.8); or (ii) approve of the changes. Failure of Client to approve changes or otherwise respond in a timely manner may result in: (i) delay in the Product Availability Date; or (ii) loss of a Production slot in Catalent's schedule; but in either case shall not relieve Client of its obligations to pay Catalent for all activities described in the applicable Project Plan, including any lost Production slot.

3.10.2 **Product-Specific Changes**. If Facility, equipment, process or system changes are required of Catalent as a result of requirements set forth by the FDA or any other applicable Regulatory Authority, and such changes apply exclusively to the Production and supply of one or more Products, then Client and Catalent will review such requirements. If Client agrees in writing to such changes, then Client shall bear [***] percent of the reasonable costs of implementation thereof. If Client does not agree to such regulatory changes, Client may terminate this Agreement upon written notice to Catalent, in which case Client shall pay Catalent for all activities described in the applicable Project Plan, including any Missed Slot, in each case, if required under and in accordance with Section 3.8.

3.10.3 **General Changes**. If such changes apply generally (i.e., to one or more Products as well as to other products Produced by Catalent for itself or for third parties), and Client agrees to such regulatory changes, then Catalent shall make such changes. If Client does not agree to such regulatory changes, Client may terminate this Agreement upon written notice to Catalent, in which case Client shall pay Catalent for all activities described in the applicable Project Plan, including any Missed Slot, in each case, if required under and in accordance with Section 3.8.

3.11. **Delivery Terms**. Product shall be delivered to Client EXW (Incoterms, 2010) Facility, addressed to a location designated by Client. Product shall be delivered to a common carrier designated by Client on the shipment request form or Project Plan, at Client's expense. Client shall procure, at its cost, insurance covering damage or loss to the Product during shipping. Title for Product shall pass to Client upon Catalent's Quality Disposition of Product. If Catalent arranges shipping or performs similar loading and/or logistics services for Client at Client's request, such services are performed by Catalent as a convenience to Client only and do not alter the terms and limitations set forth in this section. Catalent shall not be responsible for Product in transit, including any cost of insurance or transport fees for Product, or any risks associated with transit or customs delays, storage and handling.

3.12. **Audit**. During the Term and for one (1) year thereafter, once per calendar year upon [***] days prior written notice, Client through its personnel or its designated representatives shall have the right to conduct an audit of that portion of each Facility used in the Production or performance of the Services during normal business hours to review Catalent's Production operations and to assess its compliance with CGMP, Applicable Laws and the Quality Agreement. Catalent shall provide Client with copies of Catalent's Production

records relating to the Product, including Batch documentation and other requested information, to be used for the purposes of the audit. In the event there have been material quality issues with Product or Production, Client may reasonably require more frequent audits of that Facility. However, if Catalent has failed to correct any discovered non-conformance (or taken reasonable measures to implement a plan to correct the non-conformance) within [***] days of the event or audit which provided Catalent with notice of such non-conformance, Client will have the right to terminate the Agreement pursuant to Section 10.2.1. Notwithstanding the foregoing notice period, for purposes of confidentiality, safety and to avoid the possibility of contamination, if a third party's product is being manufactured during the time that Client intends to conduct an audit, such audit may be reasonably delayed upon at least [***] days' prior written notice to Client. When conducting an audit, each of Client's representatives will: (a) be subject to a nondisclosure obligation at least as restrictive as the obligations contained in Article 8 ("Confidentiality and Non-Solicitation of Employees") (b) follow such security and Facility access procedures as reasonably designated by Catalent; (c) be accompanied by a Catalent representative; (d) provided that Catalent has given Client notice in accordance with the previous sentence, not enter areas of the Facility at times when any third party's products are being manufactured to assure protection of the Catalent Confidential Information or the confidential information of a third party; and (e) use reasonable efforts to avoid disrupting Catalent's operations. In addition to an audit by Client, Catalent agrees to reasonably cooperate with applicable Regulatory Authorities and shall permit reasonable Product-specific inspections by such Regulatory Authorities. While Catalent will provide access to the Facility as set forth herein for the purposes of this Section 3.12, for the avoidance of doubt, access to classified (for GMP purposes) areas of the Facility, areas that do not relate to the Services, and areas in which confidential work for other Catalent customers is taking place is at Catalent's sole discretion.

3.13. Dedicated Equipment.

3.13.1 Selection and Procurement. To the extent that Catalent is required to purchase any Dedicated Equipment, Catalent shall select and procure the Dedicated Equipment at Client's sole cost [***]. Catalent shall use [***] efforts to determine whether the Dedicated Equipment conforms to the applicable specifications and will work in the Facility for purpose stated in the Project Plan.

3.13.2 **Use and Storage of Dedicated Equipment**. Catalent shall use and store the Dedicated Equipment in accordance with any written instructions prescribed by Client or the manufacturer of the Dedicated Equipment, and shall perform such routine maintenance and storage for the Dedicated Equipment as is reasonably required by such written instructions and be reimbursed by Client for routine maintenance and storage as set forth in a Project Plan. All costs for any extraordinary or non-routine maintenance that may be required will be approved in advance by Client, and the appropriate Project Plan will be revised to reflect any additional maintenance costs that may be required during the Term. Except: (i) in connection with such routine maintenance and storage; or (ii) as directed in writing by Client; Catalent shall not make any alterations, additions or improvements to the Dedicated Equipment. All directed alterations, additions or improvements made to the Dedicated Equipment will be at Client's sole cost and expense.

3.13.3 **Ownership and Risk of Loss; Disposition of Equipment**. Client shall own and continue to own all right, title and interest in and to any Dedicated Equipment. Client assumes any risk of loss, damage, theft or destruction of the Dedicated Equipment while that Dedicated Equipment is in Catalent's possession or on Catalent's premises; except that Client hereby expressly disclaims liability, and Catalent shall be liable, for any and all loss, damage, theft or destruction of Dedicated Equipment resulting from Catalent's negligence, gross negligence, or willful misconduct. Upon termination or expiration of this Agreement, Client shall have the right and obligation, upon reasonable notice, to reclaim possession of such Dedicated Equipment at its sole expense (including all costs of disconnection, removal, physical transfer and any subsequent reinstallation and requalification costs). Catalent shall reasonably cooperate with Client to remove and return such Dedicated Equipment to Client in accordance with Client's written instructions and shall invoice Client for: (i) direct costs incurred; and (ii) any damage other than reasonable wear and tear to the Facility incurred as a result of the installation and/or removal of the Dedicated Equipment. Notwithstanding the above, upon termination or expiration of this Agreement, Client may offer to sell to Catalent, or Catalent may offer to purchase from Client, the Dedicated Equipment at its then depreciated cost or fair market value, whichever is less. Neither Catalent nor Client shall be

obligated to make or accept such offers. In the event that Client has not removed the Dedicated Equipment within [***] days after reasonable notice, the Dedicated Equipment shall be deemed to be abandoned and Catalent may dispose of it or use it as it sees fit.

3.14. Product Testing.

3.14.1 **Testing**. Catalent (or one or more of its Affiliates) shall test, or cause to be tested by third party testing facilities audited and approved by Catalent, in accordance with the Product Specifications, each Batch of Product Produced pursuant to this Agreement before delivery to Client. A Certificate of Analysis for each Batch of Product delivered to Client shall set forth the items tested by Catalent, specifications, and test results. Catalent shall send, or cause to be sent, such certificates along with one (1) copy of the Batch Record Package to Client prior to or at the same time of shipment of Product to Client and within [***] calendar days after the date of fill if such Batch requires no investigations and/or additional testing. For the avoidance of doubt, Client is solely responsible for final release of each lot of the Product.

3.14.2 **Stability Testing**. At Client's cost and expense, Catalent or a party selected by Client may perform all stability testing required to be performed on Production Batches of Product. If performed by Catalent, such testing shall be performed in accordance with the procedures set out in the Product-specific Client-Specific SOPs for the stability protocol and the Project Plan.

4. Nonconforming Product.

4.1. Product Conformity.

4.1.1 **Testing and Acceptance**. Subject to Section 4.4 ("Nonconforming Development/Engineering Batch"), Client shall have [***] calendar days from receipt by Client of: (i) representative samples of Product intended for release testing by Client; (ii) the Batch Record Package; or (iii) each Unit of Product, to determine whether such Product (a) conforms to the relevant Product Specifications and (b) was manufactured in compliance with CGMP, as applicable (collectively the "**Product Requirements**"). If Client believes any shipment

of Product does not conform to the Product Requirements ("**Nonconforming Product**"), then Client shall give Catalent written notice thereof as soon as practicable but in no event later than [***] days from the date of such determination by Client (an "**Exception Notice**") and shall, unless otherwise directed by Catalent, return the Product (if it was shipped) for further testing by Catalent. Failure to timely provide an Exception Notice and return of the Unit for further testing by Catalent shall constitute an acceptance by Client of such Unit; [***], that [***] be [***] with respect to [***] that are not [***] by the [***] of [***] and [***]. Catalent shall conduct its own testing of the rejected Product or Unit(s), as applicable, within [***] days of receipt thereof, and if Catalent agrees, or it is determined pursuant to Section 4.1.2 ("Disputes"), that the Product is a Nonconforming Product as a result of Catalent's negligence, gross negligence, or willful misconduct ("**Catalent Nonconforming Product**"), the applicable provisions of Section 4.2 ("Remedies for Nonconforming Product") shall apply. If, after conducting its own testing, Catalent determines, or it is determined pursuant to Section 4.1.2 ("Disputes"), that the Nonconforming Product is not a Catalent Nonconforming Product, then the applicable provisions of Section 4.3 ("Remedies for Nonconforming Product") shall apply.

4.1.2 **Disputes**. If the Parties disagree as to whether Product meets Product Requirements and/or is Nonconforming Product or Catalent Nonconforming Product, and this is not resolved within [***] days of Catalent's receipt of an Exception Notice, the Parties shall cause a mutually acceptable independent third party to review records and test data and to perform comparative tests and/or analyses on samples of such Product, including (as appropriate) any Client Materials, Raw Materials, Process Consumables, and Components. The independent party's results as to whether Product or Unit meets Product Requirements or is a Nonconforming Product or Catalent Nonconforming Product, and the cause of any nonconformity, shall be final and binding. Unless otherwise agreed to by the Parties in writing, the costs associated with such testing and review shall be borne by Catalent if Product is deemed by the independent party to be Catalent Nonconforming Product, and by Client in all other circumstances. For avoidance of doubt, where the cause of nonconformity cannot be determined or assigned, the Product shall not be deemed to be Catalent Nonconforming Product.

4.2. **Remedies for Catalent Nonconforming Product**. If a Product is determined to be Catalent Nonconforming Product (whether by agreement of Catalent pursuant to Section 4.1 ("Product Conformity") or by an independent expert pursuant to Section 4.1.2 ("Disputes")), the Parties will negotiate in good faith whether such Catalent Nonconforming Product shall be returned to Catalent, destroyed, or retained by Client, and the terms that shall govern the chosen course of action. Additionally:

4.2.1 **Drug Product**: If the Drug Substance met or is deemed to meet Product Requirements, but the Drug Product constitutes Catalent Nonconforming Product, [***] shall [***] the [***] at [***] for [***]. In the re-performance of its Drug Product Services, Catalent shall use replacement Bulk Drug Substance, Raw Materials, Process Consumables, and Components. Regardless of whether such replacement Bulk Drug Substance, Raw Materials, Process Consumables, and Components are provided by Client or Catalent, [***] the [***] of the [***] and [***] the [***] of the [***] , and [***]. The remedies described in this Section 4.2.1 shall be Client's sole remedies under this Section 4.2.1.

4.2.2 **Replacement**. In each such case, Catalent shall use [***] efforts to replace such Nonconforming Product in a reasonable time given any commitments to other Catalent clients or contractually obligated capacity constraints.

4.3. **Remedies for Other Nonconforming Product**. In the event a Product is determined to be Nonconforming Product (whether by agreement of Catalent pursuant to Section 4.1 ("Product Conformity") or by an independent expert pursuant to Section 4.1.2 ("Disputes")), but is not determined to be Catalent Nonconforming Product, the Parties will negotiate in good faith whether such Nonconforming Product shall be returned to Catalent, destroyed, or retained by Client, and the terms that shall govern the chosen course of action. Additionally:

4.3.1 Catalent shall re-perform the Services with respect to the Nonconforming Product at Client's option and expense with Client bearing the cost of Bulk Drug Substance, other Raw Materials, Process Consumables, Components, and the Services of Catalent including the Batch Price for the Nonconforming Product. Client shall be responsible for the cost of each Batch of such Nonconforming Product.

4.3.2 In each such case, Catalent shall use [***] efforts to replace such Nonconforming Product in a reasonable time given any commitments to other Catalent clients or contractually obligated capacity constraints.

4.4. **Nonconforming Development/Engineering Batch**. Client shall be responsible for the cost of each Development/Engineering Batch, whether or not Product from the Development/Engineering Batch is delivered (provided that Client shall not be responsible for the cost of a Development/Engineering Batch that was not delivered because of a failure that was caused by the gross negligence of Catalent or as a result of a Catalent equipment or facility malfunction ("**Catalent Development/Engineering Batch Failure**")). Catalent and Client shall cooperate in good faith to resolve any problems causing any out-of-Specification Development/Engineering Batch. Except with respect to a Catalent Development/Engineering Batch Failure, Catalent shall have no obligation to re-perform any Services for a Development/Engineering Batch. If Catalent re-performs any Services, and Client approves such re-performance in writing, Client shall be responsible for the cost of all Raw Materials and/or Components and Client shall supply Catalent with sufficient quantities of any Client-Supplied Raw Materials and Components in order for Catalent to re-perform such Services.

4.5. **Nonconforming Client Materials**. If a Product's failure to meet the Product Requirements (whether or not such Product has been given a Quality Disposition of "released") is the sole and direct result of nonconforming Client Materials (including by not limited to Bulk Drug Substance), then such nonconformity shall not be deemed the responsibility of Catalent for purposes of this Article 4 ("Nonconforming Product"), and notwithstanding Section 4.1 ("Product Conformity") above, Client shall pay Catalent's invoice for such Product, and Catalent shall not be required to bear the cost of replacing the nonconforming Product pursuant to Section 4.2 ("Remedies for Catalent Nonconforming Product").

5. Price and Payment.

5.1. **Product Price**. The price to be paid by Client for Units of Product ("**Price**") shall be set forth in the Project Plan, accepted purchase order, or as otherwise agreed to in writing between the Parties. Each calendar year, Catalent may, at its sole discretion, increase or decrease the Price of any Product that is not covered by a Firm Order as of the effective date of the Price increase or decrease.

5.2. **Cost Reimbursement**. For all pass-through and out-of-pocket costs specified in the Project Plan (which may include but is not limited to Raw Materials, Catalent-Supplied Components, filters, containers, Product-contact disposables, and Dedicated Equipment) Client shall reimburse Catalent, at Catalent's cost [***].

5.3. **Payment Terms**. Catalent shall generate invoices for all fees and cost reimbursements. Invoices for Product will be sent in accordance with the milestones set forth in the Project Plan, and in any case not later than Catalent's Quality Disposition of each Batch of Product. Each such invoice will provide a reasonable level of detail and itemize the status of each activity and milestone as detailed in the Project Plan. Invoices for cost reimbursement will be sent not less than monthly and include reasonable documentation of costs incurred. Client shall pay undisputed invoices [***] of the invoice date. If any payment is not received by Catalent by its due date, then Catalent may, in addition to other remedies available at equity or in law, charge interest [***] on the outstanding sum until paid in full, calculated from the scheduled payment due date forward; provided that in no event shall such annual rate exceed the maximum interest rate permitted by Applicable Laws in regard to such payments. Such payments when made shall be accompanied by all interest so accrued. Client shall make all payments electronically through the Automated Clearing House (ACH) Network in U.S. Dollars, or otherwise as directed in the applicable invoice.

5.4. **Regulatory Services Price**. The price to be paid by Client for regulatory services shall be set forth in a Project Plan.

5.5. **Default in Payment Obligations**. In addition to all other remedies available to Catalent in the event of a Client default, if Client fails to make undisputed payments as required hereunder, Catalent may refuse all further orders and may refuse to Produce any Product until Client's account is paid in full.

5.6. **Insurance**. Each Party shall, at its own cost and expense, obtain and maintain in full force and effect during the Term the following: (A) Commercial General Liability Insurance with a per occurrence limit of $[***] and an annual aggregate limit of $[***]; (B) Products and Completed Operations Liability Insurance with a per occurrence limit of not less than $[***]; (C) Workers' Compensation Insurance with statutory amounts and Employers Liability Insurance with limits of not less than $[***] per accident; and (D) Auto Liability insurance for owned, hired and non-owned vehicles in a minimum amount of $[***] combined single limit. Client shall, at its own cost and expense, obtain and maintain in full force and effect during the Term, All Risk Property Insurance, including transit coverage, in an amount equal to the full replacement value of its property at all times whether in transit to, or from, a Facility, between Facilities, or present at a Facility. Client shall obtain a

waiver of subrogation clause from its property insurance carrier in favor of Catalent. Each Party may self-insure all or any portion of the required insurance as long as, together with its Affiliates, its US GAAP net worth is greater than $[***] or its annual EBITDA (earnings before interest, taxes, depreciation and amortization) is greater than $[***]. If any required insurance policy is written on a claims-made basis, such policy shall be maintained throughout the Term and for a period of at least [***] years thereafter. Each Party shall be named as an additional insured within the other Party's products liability insurance policies. Waivers of subrogation and additional insured status obligations will operate the same whether insurance is carried through third parties or self-insured. Upon the other Party's written request from time to time, each Party shall promptly furnish to the other Party a certificate of insurance or other evidence of the required insurance or qualification to self-insurance in accordance with the requirements of this Article 5 ("Price and Payment"). Each insurance policy that is required under this Agreement shall be obtained from an insurance carrier with an A.M. Best or equivalent rating of at least A- VII or an S&P rating of A.

5.7. **Taxes**. Unless otherwise indicated in writing by Catalent, all prices and charges are exclusive of any applicable taxes, levies, import duties, Goods and Services Tax (GST), Value Added Tax (VAT), and fees of whatever nature, imposed by or under the authority of any governmental body, all of which shall be paid by Client (other than taxes on Catalent's net income). If applicable, Indiana sales tax shall be charged on all applicable transactions unless Client has provided to Catalent a properly completed Indiana Exemption Certificate (Form ST-105). To the extent that Client owns any Dedicated Equipment or other personal property located at the Facility that is subject to property tax, Catalent may be obligated to report such property and Client shall be obligated to file and pay all applicable Monroe County, Indiana property taxes. If any deduction or withholding in respect of any tax or otherwise is required by law to be made from the amounts payable under this Agreement, Client shall be obliged to pay to Catalent such greater sum as will leave Catalent, after such required deduction or withholding is made, with the same amount as it would have been entitled to receive in the absence of any such required deduction or withholding obligation.

6. Representations and Warranties.

6.1. **Mutual Representations and Warranties**. Each Party hereby represents and warrants to the other Party as follows:

6.1.1 Such Party is duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is organized.

6.1.2 Such Party (i) has the requisite power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder, and (ii) has taken all necessary action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder.

6.1.3 This Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms.

6.1.4 All necessary consents, approvals and authorizations of all governmental authorities and other Persons required to be obtained by such Party in connection with this Agreement have been obtained.

6.1.5 The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (i) do not and will not conflict with or violate any requirement of Applicable Laws or regulations and (ii) do not and will not conflict with, or constitute a default under, any contractual obligation of such Party. Catalent has informed Client, and Client acknowledges, that Catalent is a US Government contractor and that in an emergency declared by the US Government, Catalent may be obligated to give US Government production requirements priority over other production orders. If this occurs, it shall not be deemed a breach by Catalent of its representations and warranties under this clause, or under any other section of this Agreement.

6.1.6 Each Party represents, warrants and covenants that it shall not employ, contract with, or retain any person directly or indirectly to perform any services under this Agreement if: (i) such person is presently debarred by the FDA pursuant to 21 U.S.C. § 335a and b or its successor provisions, or the party has knowledge that such a person is under investigation by the FDA for debarment; or (ii) such a person has a disqualification hearing pending or has been disqualified by the FDA pursuant to 21 CFR § 312.70 or its successor provisions. In addition, each Party represents, warrants and

covenants that it has not and shall not engage in any conduct or activity which could reasonably lead to any of the above-mentioned disqualification or debarment actions. If, during the Term, either party or any person employed or retained by it to perform the Services: (A) comes under investigation by the FDA for a debarment action or disqualification; (B) is debarred or disqualified; or (C) engages in any conduct or activity that could lead to any of the above-mentioned disqualification or debarment actions, such Party shall immediately notify the other Party of same.

6.1.7 No transaction or dealing under this Agreement shall be conducted with or for an individual, entity or a country that is designated as the target of any sanction, restriction or embargo administered by the United Nations, European Union, United Kingdom or United States of America.

6.2. Representations and Warranties of Client. Client further represents and warrants, and covenants that:

6.2.1 Client has lawful access to and the right to license or sublicense the Client Confidential Information, Client Intellectual Property Rights and Client Materials to Catalent under this Agreement.

6.2.2 Client is not subject to any written claim or notice of infringement or misappropriation of any third party intellectual property rights relating to the Client Confidential Information, Client Intellectual Property Rights or Client Materials used by Catalent under this Agreement.

6.2.3 [***] each of the making, having made, use or importation of the Product and/or the Client Materials in accordance with the Project Plan and this Agreement do not infringe or misappropriate any third party intellectual property rights.

6.2.4 The biological and chemical properties of the Client Materials have been evaluated prior to the Effective Date and, to Client's knowledge, the Client Materials are safe and non-hazardous for purposes of the Services to be performed hereunder.

6.3. Representations and Warranties of Catalent. Catalent shall perform all Services in accordance with Applicable Laws. Except with respect to a Development/Engineering Batch, Catalent represents, warrants and covenants that: (a) the Production shall be performed in accordance with Section 3.2 ("Performance") and (b) the Product when made available at Catalent's shipping docks shall: (i) meet Product Specifications; (ii) have been Produced in accordance with CGMP and Applicable Laws; and (iii) at the time of delivery, shall be free and clear of any lien or encumbrance. Catalent further represents, warrants, and covenants that (A) Catalent owns, or holds sufficient rights to use for the purposes of Production of the Product, all Catalent Intellectual Property used by Catalent in the Production of the Product pursuant to this Agreement, (B) such Catalent Intellectual Property does not infringe the intellectual property rights of any third, and (C) all Permitted Subcontractors utilized by Catalent in fulfillment of its obligations under this Agreement are obligated to assign any intellectual property developed hereunder to Catalent. EXCEPT FOR ANY REPRESENTATIONS AND WARRANTIES IN THIS AGREEMENT, CATALENT HEREBY EXPRESSLY DISCLAIMS ALL OTHER REPRESENTATIONS OR WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR ARISING FROM A COURSE OF DEALING OR USAGE OR TRADE PRACTICE, WITH REGARD TO ANY PRODUCT DELIVERED HEREUNDER, WHETHER USED ALONE OR IN COMBINATION WITH OTHER SUBSTANCES OR NON-INFRINGEMENT OF THE PATENT RIGHTS OR OTHER INTELLECTUAL PROPERTY RIGHTS OF ANY OTHER PERSON.

7. Indemnification; Limitation of Liability; Waiver of Subrogation.

7.1. **Client Indemnification**. Subject to the limitations set forth in Section 7.4, Client shall indemnify, defend and hold harmless Catalent against any Damages, whether or not foreseeable or in the contemplation of Catalent or Client, that Catalent suffers as a result of any third party Claims arising out of: (a) any material breach of the representations and warranties set forth in Sections 6.1 ("Mutual Representations and Warranties") and 6.2.4; (b) the distribution or use of the Product Produced by Catalent under this Agreement; (c) Product Liability Claims; (d) negligence (active, passive or imputed), gross negligence or willful misconduct of Client in relation to the use, processing, storage or sale of the Product Produced by Catalent under this Agreement; and/or (e) any claims by third parties alleging Catalent's use of the Client Materials, Client Confidential Information, Client Intellectual Property Rights or the Product Specifications in accordance with the Project Plans and this Agreement infringes any intellectual property rights of any third party (whether or not Client knew or should have known about such alleged infringement). This indemnification obligation shall not apply to the extent that such Claims arise

out of: (i) Catalent's production techniques while performing the Services; or (ii) a modification of the Client Materials, Client Confidential Information, Client Intellectual Property Rights or the Product Specification that is not approved by Client. Client shall have no obligation to indemnify, defend or hold harmless Catalent in accordance with this Section 7.1 to the extent that any Damages are caused by Catalent's negligence (active, passive or imputed), gross negligence or willful misconduct or the breach by Catalent of any warranty, representation, or covenant made by Catalent in this Agreement.

7.2. **Catalent Indemnification**. Subject to the limitations set forth in Section 7.4, Catalent shall indemnify, defend and hold harmless Client against any Damages, whether or not foreseeable or in the contemplation of Client or Catalent, that Client may suffer as a result of any third party claims, suits or actions arising from: (a) Catalent's breach of the representations and warranties in Sections 6.1 ("Mutual Representation and Warranties") and 6.3 ("Representations and Warranties of Catalent"); (b) negligence (active, passive or imputed), gross negligence or willful misconduct of Catalent in performance of the Services; and/or (c) any claims by third parties alleging Catalent's Production techniques while performing the Services infringe any intellectual property rights of any third party (whether or not Catalent knew or should have known about such alleged infringement). This indemnification obligation shall not apply to the extent the Damages are a result of: (i) Client's negligence (active, passive or imputed); (ii) Catalent's use of an application or production technique that has been provided by Client; or (iii) Catalent's use of Client Materials.

7.3. **Procedure for Indemnification**. A Party (the "**Indemnitee**") that intends to claim indemnification under Sections 7.1 ("Client **Indemnitee** Indemnification") or 7.2 ("Catalent Indemnification") shall promptly notify the other Party (the "**Indemnitor**") of any Claim for which the Indemnitee intends to claim such indemnification. The Indemnitee shall have the right to retain its own counsel, at its own cost, to participate in the defense of any Claim. The indemnity obligations under Sections 7.1 ("Client Indemnification") and 7.2 ("Catalent Indemnification") shall not apply to amounts paid in settlement of any claim, demand, action or other proceeding if such settlement is effected without the prior express written consent of the Indemnitor, which consent shall not be unreasonably withheld or delayed. The failure to deliver notice to the Indemnitor within a reasonable time after notice of any such Claim, or the commencement of any such action or other proceeding, if materially prejudicial to its ability to defend such claim, demand, action or other proceeding, shall relieve such Indemnitor of any liability to the Indemnitee under Sections 7.1 ("Client Indemnification") and 7.2 ("Catalent Indemnification") with respect thereto, but the omission so to deliver notice to

the Indemnitor shall not relieve it of any liability that it may have to the Indemnitee otherwise than under Sections 7.1 ("Client Indemnification") and 7.2 ("Catalent Indemnification"). The Indemnitor may not settle or otherwise consent to an adverse judgment in any such Claim without the prior express written consent of the Indemnitee, which consent shall not be unreasonably withheld or delayed. The Indemnitee, its employees and agents shall reasonably cooperate with the Indemnitor and its legal representatives in the investigation and defense of any claim, demand, action or other proceeding covered by this Section 7.3 ("Procedure for Indemnification").

7.4. Limitation of Liability.

7.4.1 **DISCLAIMER OF SPECIAL DAMAGES**. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY OR TO ANY THIRD PARTY UNDER THIS AGREEMENT FOR ANY PUNITIVE DAMAGES OR SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES (INCLUDING LOST PROFITS, BUSINESS OR REVENUE) EVEN IF ADVISED OR AWARE OF THE POSSIBILITY OF SUCH DAMAGES.

7.4.2 **Direct Damage Limitation**. The liability of Catalent to Client, its permitted assigns and successors in interest, for any Damages suffered by Client or its permitted assigns and successors in interest, arising as a direct result of a breach of this Agreement, or of any other liability, including misrepresentation and negligence, arising out of this Agreement and the Services provided hereunder, including the production or supply of Product and Catalent's liability under Section 7.2 ("Catalent Indemnification"), shall be limited to: (i) [***] the [***] amount [***] by [***] from [***] for [***] for the [***] that [***] to the [***]; (ii) [***] dollars ($[***]) in the event of loss of [***] as set forth in [***]; or (iii) [***] Dollars ($[***]) (in the case of [***] not covered by (i) or (ii) above) [***].

7.5. Abatement. Notwithstanding anything to the contrary in this Agreement, in the event that Production is held, in a suit or proceeding, to infringe any intellectual property rights of a third party (or to constitute the misappropriation of a trade secret of a third party) and Production is enjoined, or Catalent has an objective basis (confirmed by an opinion of its legal counsel) for believing that it is likely to be found to infringe or constitute a misappropriation, or is likely to be enjoined, then Catalent shall, at its option,

either: (i) procure the right to continue Production; or (ii) modify the Production so that it becomes non-infringing or no longer constitutes a misappropriation, provided that such modification has no adverse effect on Client hereunder; provided, however, that if (i) and (ii) are not reasonably practicable, then Catalent shall notify Client and Client shall have the right, in its sole discretion, to terminate this Agreement, effective upon the date the notice is given, by giving Catalent prior written notice of the termination. Client shall have no obligations to make any additional payments, including any payments for Firm Order made but not fulfilled, after the effective date of such termination.

7.6. **Waiver of Subrogation**. All Catalent Supplied Components and equipment (other than Dedicated Equipment owned by Client) used by Catalent in the Production of Product (collectively, "**Catalent Property**") shall at all times remain the property of Catalent and Catalent assumes risk of loss for such property until delivery of Product to a common carrier as specified under Section 3.11 ("Delivery Terms"). Catalent hereby waives any and all rights of recovery against Client, or against its directors, officers, employees, agents or representatives, for any loss or damage to Catalent Property to the extent the loss of damage is covered or could be covered by insurance (whether or not such insurance is described in this Agreement). Client assumes all risk of loss for all Client Materials, Dedicated Equipment owned by Client, and all Product that are in Client's possession (collectively, "**Client Property**"). Client hereby waives any and all rights of recovery against Catalent, or against its directors, officers, employees, agents or representatives, for any loss or damage to the Client Property to the extent the loss of damage is covered or could be covered by insurance (whether or not such insurance is described in this Agreement).

7.7. **Limitations an Essential Element of the Agreement**. The Parties are willing to enter into this Agreement only in consideration of and in reliance upon the provisions of this Agreement limiting their exposure to loss or liability. Such provisions are an essential part of the bargain underlying this Agreement and have been reflected in the pricing and other consideration specified in this Agreement. Both Parties understand and agree that the exclusion of warranties, limitation of liability and the limitation of remedies allocate risks between the Parties as authorized under Applicable Laws.

8. Confidentiality and Non-Solicitation of Employees.

8.1. **Confidential Information**. Each Party agrees that during the Term of this Agreement and for a period of [***] years thereafter, it will keep the Confidential Information of the other Party secret and confidential in accordance with the terms and conditions of this Agreement, respect the other

Party's proprietary rights therein and make use of and permit to be made use of such information and material only as necessary to perform its obligations and exercise its rights under this Agreement. Neither Party may disclose or permit the Confidential Information of the other Party to be disclosed to any third party except as expressly provided herein without the other Party's prior written consent.

8.2. **Disclosure of Confidential Information**. Client and Catalent shall grant access to the other Party's Confidential Information only to its Affiliates, employees and Permitted Subcontractors who reasonably need to know such information for purposes such Party's exercise of its rights or performance of its obligations under this Agreement and who are subject to written obligations of confidentiality with respect to which Confidential Information no less restrictive than those set forth in this Article 8.

8.3. **Exceptions to Confidentiality**. The obligations of Article 8 shall not apply to Confidential Information to the extent that it:

8.3.1 is now, or hereafter becomes, through no act or failure to act on the part of the receiving Party in breach of Article 8 ("Confidential Information and Non-Solicitation of Employees"), generally known or available;

8.3.2 is known by the receiving Party at the time of receiving such Confidential Information, as shown by contemporaneous written records;

8.3.3 is furnished after the Effective Date to the receiving Party by a third party, without breach of and not subject to any obligation of confidentiality; or

8.3.4 is independently developed by the receiving Party without use of or reference to Confidential Information of the other Party, as shown by independent written records, contemporaneous with such development.

In addition, the receiving Party may disclose the disclosing Party's Confidential Information to the extent that it is compelled to do so under any statutory, regulatory, stock exchange or similar legislative requirement or court order, provided, however, that (i) the receiving Party gives the disclosing Party prior written notice of such required disclosure (to the extent permitted) and assists the disclosing Party in its reasonable efforts to prevent or limit such disclosure; and (ii) the Confidential Information so disclosed otherwise remains the Confidential Information of the disclosing Party for the purposes of Article 8 ("Confidentiality and Non-Solicitation of Employees").

8.4. **Return of Confidential Information**. Upon any expiration or termination of this Agreement, each Party will use diligent efforts (including without limitation a diligent search of files and computer storage devices) to return or destroy all Confidential Information of the other Party and all copies, summaries, compilations, extracts or other derivatives thereof, except to the extent such Confidential Information is necessary to exercise any right surviving termination of this Agreement. Additionally, each Party will be allowed to keep one archival copy of any Confidential Information of the other Party solely for record keeping and for the purpose of determining its rights and obligations hereunder.

8.5. **Restrictions on Soliciting Catalent Employees**. During the Term of the Agreement and for [***] months after the Agreement terminates or expires, Client shall not, directly or indirectly, solicit, hire, employ or attempt to solicit, hire or employ any person who is or was an employee of Catalent during the Term (or the following [***] months), or in any other way directly or indirectly seek to solicit, induce, bring about, influence, promote, facilitate, or encourage any such individual to work for Client or any party other than Catalent. The foregoing limitation shall not apply with respect to any general solicitations for employment made by Client.

8.6. **Remedies**. Each Party acknowledges and agrees that the other Party may not have an adequate remedy at law for a violation of this Article 8 (“Confidentiality and Non-Solicitation of Employees”) and therefore shall be entitled to seek enforcement of this Article 8 (“Confidentiality and Non-Solicitation of Employees”) by temporary or permanent injunctive or mandatory relief obtained in any court of competent jurisdiction without the necessity of proving Damages, and without prejudice to any other rights and/or remedies which may be available to such Party at law or in equity.

8.7. **Use of Name**. Except as set forth in Section 9.6 (“Trademarks”), neither Party shall use the name or trademarks of the other Party, except to the extent that a Party is permitted to use the Confidential Information of the other Party or required to do so pursuant to this Article 8 (“Confidentiality and Non-Solicitation of Employees”), without the prior written consent of such other Party, such consent not to be unreasonably withheld. Under no circumstances shall either Party state or imply in any promotional material, publication or other published announcement that the other Party has tested or approved any product.

9. Intellectual Property.

9.1. **Disclosure**. Catalent shall disclose to Client any and all Product Inventions made pursuant to the activities undertaken relating to this Agreement promptly after each such Invention is developed, conceived, or reduced to practice.

9.2. **Catalent Intellectual Property Rights**. As between the Parties, Catalent shall solely own all right, title and interest in and to the Catalent Intellectual Property Rights. Catalent hereby grants Client a non-exclusive, perpetual, irrevocable, fully paid-up, sublicensable, royalty-free license under the Catalent Intellectual Property Rights solely for the purpose of using, offering for sale, selling, exporting, and/or importing Product supplied by Catalent. Client shall not, without Catalent's prior written consent, use the Catalent Intellectual Property Rights for any purpose other than as stated herein.

9.3. **Client Intellectual Property Rights**. As between the Parties, Client shall solely own all right, title and interest in and to the Client Intellectual Property Rights. Catalent shall not, without Client's prior written consent, use the Client Intellectual Property Rights for any purpose other than Services as contemplated in this Agreement, including in Section 2.3 ("License Grant").

9.4. **Inventions**. All Project Inventions shall be owned by Catalent. Client hereby assigns and agrees to assign all of its ownership rights in and to the Project Inventions to Catalent. To the extent that a Project Invention is patentable, Catalent shall have the right (but not the obligation) to file, prosecute and maintain any patents or patent applications claiming or covering any Project Invention. All Product Inventions shall be owned by Client. Catalent hereby assigns and agrees to assign all of its ownership rights in and to the Product Inventions to Client. Client shall have the right but not the obligation to file, prosecute and maintain any patents or patent applications claiming all Product Inventions. Each Party shall bear the expense of activities relating to its own filing, prosecution and maintenance of any patent or patent applications provided for by this Section 9.4 ("Inventions"). Each Party shall execute all writings or take such acts, at the other Party's expense, as may be reasonably required for either Party to fully enjoy the rights and licenses granted pursuant to this Section 9.4 ("Inventions").

9.5. **No Implied Licenses**. Except as expressly set forth in this Agreement, nothing contained in this Agreement shall be construed as granting, by implication, estoppel or otherwise, any licenses or rights under any patents or other intellectual property rights. Only licenses and rights granted expressly herein shall be of legal force and effect.

9.6. Trademarks.

9.6.1 Catalent License. Subject to the terms and conditions of this Agreement, Client grants to Catalent a non-exclusive, non-sublicensable (except to Permitted Subcontractors) royalty free license during the Term to use the Client Trademarks for the sole purpose of allowing Catalent to fulfill its responsibilities under this Agreement. Such license shall not be transferable in whole or in part. Catalent may only use the Client Trademarks in accordance with any usage guidelines that Client provides to Catalent from time to time. Catalent agrees that all goodwill arising out of the use of the Client Trademarks will accrue to the sole benefit of Client.

9.6.2 Client Ownership. Client shall be solely responsible for selecting, registering and enforcing the Client Trademarks used to identify the Product, except as set forth in Section 9.6.1 ("Catalent License"), and shall have sole and exclusive rights in such Client Trademarks.

9.7. Ownership of Information. All information not in the public domain, including ideas, discoveries, inventions, data, formulae, techniques, procedures for experiments and tests, designs, sketches, records, biological processes and analyses, whether or not patented or eligible for patent protection ("**Information**") developed by Catalent pursuant to this Agreement, including all interim reports and final reports, any data, records relating exclusively to Batches of the Product, and analytical methods and specifications and all copies thereof, shall be the sole property of Client. Catalent shall provide to Client copies of Information and access to Information in accordance with the terms of this Agreement. All records generated by or delivered to Catalent that are not subsequently delivered to Client shall be retained by Catalent for any retention period required by Applicable Laws.

10. Term and Termination.

10.1. Term. This Agreement shall be effective on the Effective Date and shall continue for thirty-six (36) months thereafter (the "**Initial Term**"), unless earlier terminated in accordance with the terms of this Agreement. This Agreement will be renewed for successive twelve (12) month periods commencing at the expiration of the Initial Term and any extensions thereof unless either the Client or Catalent gives the other Party written notice of intent not to renew the Agreement at least ninety (90) days prior to the expiration of the Initial Term or any extension thereof. The Initial Term as may be extended is referred to herein as the "**Term**." Client may at any time terminate this Agreement for its convenience upon thirty (30) days written notice to Catalent.

10.2. Termination for Breach.

10.2.1 **Generally**. Except as provided in Section 10.2.2 ("Exhaustion"), the failure by a Party (the "**Defaulting Party**") to comply with any of the Defaulting Party's material obligations under this Agreement shall entitle the other Party (the "**Non-Defaulting Party**") to give to the Defaulting Party notice specifying the nature of the default and requiring the Defaulting Party to cure such default. If such default is not cured within thirty (30) days after the receipt of such notice (or, if such default reasonably cannot be cured within such period), the Non-Defaulting Party shall be entitled, without prejudice to any of the other rights conferred on it by this Agreement or available to it at law, in equity or under this Agreement, to terminate this Agreement by giving further notice to the Defaulting Party, to take effect immediately upon delivery thereof. The right of either Party to terminate this Agreement, as provided in this Section 10.2.1 ("Generally"), shall not be affected in any way by its waiver or failure to take action with respect to any previous default.

10.2.2 **Exhaustion**. No default based on a claimed failure of any Product to conform to the Product Specifications shall be the subject of a notice under Section 10.2.1 ("Generally") until and unless all procedures and remedies specified in Article 4 ("Nonconforming Product") shall have first been exhausted. Furthermore, no inability to supply Client with Product caused by an event of Force Majeure shall be the subject of a notice under Section 10.2.1 ("Generally").

10.3. Termination for Insolvency. Subject to any limitations imposed by applicable law, either Party shall have the right to terminate this Agreement by giving notice to the other Party in the event that:

10.3.1 Such other Party shall have: (i) voluntarily commenced any proceeding or filed any petition seeking relief under the bankruptcy, insolvency or other similar laws of any jurisdiction, (ii) applied for, or consented to, the appointment of a receiver, trustee, custodian, sequestrator, conciliator, administrator or similar official for it or for all or substantially all of its property, (iii) filed an answer admitting the material allegations of a petition filed against or in

respect of it in any such proceeding, (iv) made a general assignment for the benefit of creditors of all or substantially all of its assets, (v) become unable generally, or admitted in writing its inability, to pay all or substantially all of its debts as they become due, or (vi) taken corporate action for the purpose of effecting any of the foregoing; or

10.3.2 An involuntary proceeding shall have been commenced, or any involuntary petition shall have been filed, in a court of competent jurisdiction seeking: (i) relief in respect of such other Party, or of its property, under the bankruptcy, insolvency or similar laws of any jurisdiction, (ii) the appointment of a receiver, trustee, custodian, sequestrator, conciliator, administrator or similar official for such other Party or for all or substantially all of its property, or (iii) the winding-up or liquidation of such other Party; and, in each case, such proceeding or petition shall have continued undismissed for sixty (60) days or an order or decree approving or ordering any of the foregoing shall have continued unstayed, unappealed and in effect for thirty (30) days.

10.4. Consequences of Termination.

10.4.1 **Payments Upon and After Termination**. Upon expiration or termination of this Agreement for any reason other than as a result of Catalent's failure to comply with any of its material obligations under this Agreement or as set forth in Sections 3.11 or 7.5, Client shall pay Catalent for all work in process and Firm Orders (including all binding Project Plans and purchase orders) that are in place as of the termination date. All such payments shall be made within [***] days of invoicing by Catalent. Unless this Agreement is terminated then as a result of Catalent's failure to comply with any of the its material obligations under this Agreement or as set forth in Sections 3.11 or 7.5, upon any termination (but not expiration) of this Agreement, Client shall reimburse Catalent for all costs and expenses incurred, and all non-cancelable commitments made, in the performance of Services, including (A) any costs incurred to wind down and cease any ongoing Services and (B) all costs for purchases made by Catalent on behalf of Client. For the avoidance of doubt, if Client terminates this Agreement as a result of Catalent's failure to comply with any of its material obligations under this Agreement, Client shall have no obligations to make any additional payments (including any payments for Firm Order made but not fulfilled) under this Agreement.

10.4.2 **Effect of Termination**. In the event of any termination or expiration of this Agreement, Catalent shall provide reasonable assistance to Client to implement the transfer of Production responsibility for the Product to Client or its designee. Such reasonable assistance shall include transfer of all processes, procedures, know-how and data necessary or useful to process the Product and to Produce the Product in accordance with the Product Specifications (as in effect at the time of such termination or expiration) and FDA guidelines, including assistance of Catalent personnel in compiling and transferring this information. Such reasonable assistance will be provided by Catalent at its customary per/hour, per/person rates then in effect relative to the work to be performed.

10.5. Accrued Rights; Surviving Obligations.

10.5.1 **Accrued Rights**. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of either Party prior to such termination or expiration. Such termination or expiration shall not relieve either Party from obligations that are expressly indicated to survive termination or expiration of this Agreement.

10.5.2 **Surviving Obligations**. All of the Parties' respective rights and obligations under Sections 1 ("Definitions"), 2.3 ("License Grant") (for the period set forth therein, and subject to the terms set forth therein), 2.5 ("Ownership and Risk of Loss"), 3.6 ("No Amendment of Agreement"), 3.8 ("Cancellation of Firm Order"), 3.9.1 ("Client-Supplied Component Storage"), 3.12 ("Audit"), 3.13.3 ("Ownership and Risk of Loss; Disposition of Equipment"), 4 ("Nonconforming Product"), 5.1 ("Product Price"), 5.2 ("Cost Reimbursement"), 5.3 ("Payment Terms"), 5.6 ("Insurance"), 6 ("Representations and Warranties"), 7 ("Indemnification; Limitation of Liability; Waiver of Subrogation"), 8 ("Confidentiality and Non-Solicitation of

Employees"), 9 ("Intellectual Property"), 10.4 ("Consequences of Termination"), 10.5 ("Accrued Rights; Surviving Obligations"), 11.7 ("Records"), 11.9 ("Ownership of Regulatory Filings"), 12.2 ("Severability"), 12.3 ("Notices"), 12.4 ("Governing Law"), 12.5 ("Alternative Dispute Resolution"), 12.6 ("Entire Agreement"), 12.7 ("Attempts to Amicably Resolve Disputes"), 12.8 ("Waiver"), 12.9 ("Independent Contractors"), and 12.17 ("Quality Agreement") shall survive termination or expiration of this Agreement.

11. Regulatory.

11.1. **Permits**. Each Party shall be responsible, at its own expense, to obtain and maintain all permits and licenses required for it to carry out its obligations hereunder.

11.2. **Regulatory Approvals**. Client will diligently pursue Regulatory Approval of marketing licenses for each Product Produced by Catalent hereunder. Client will advise Catalent of document requirements in support of NDA and/or BLA and similar applications required of foreign governments and agencies including amendments, license applications, supplements and maintenance of such. Catalent will provide documents and assist Client in preparation of submissions to Regulatory Authorities (both U.S. and foreign) designated by Client in support of Client's NDAs (if any), and similar applications required of foreign governments and licenses. All regulatory submission preparation and maintenance performed by Catalent for Client shall be specified in a Project Plan for regulatory services.

11.3. **Compliance with CGMPs; Monitoring of Records**. Catalent shall monitor and maintain reasonable records respecting its compliance with CGMPs in the manner provided by the Quality Agreement, including the process of establishment and implementation of the operating procedures and the training of personnel as are reasonably necessary to assure such compliance.

11.4. **Regulatory Authority Inspections**. At Client's request, Catalent will authorize Regulatory Authorities to review related applications on Client's behalf. Catalent will notify Client within [***] calendar days of all contacts with Regulatory Authorities (both written and verbal) related to each Product. Catalent shall inform Client of the result of any regulatory inspection which directly affects the Production of a Product, including any notice of inspection, notice of violation or other similar notice received by Catalent affecting Production, Facility, testing, storage or handling of a Product. In the event of an FDA inspection which directly involves a Product, Client shall be

immediately informed of the issuance of the Notice of Inspection (FDA Form 482). In the event that there are inspectional observations (FDA Form 483), Client shall be informed immediately and shall have the opportunity to review and provide Catalent with comments to Catalent's response. Client shall provide its comments to the response of these observations within [***] business days. The contents of Catalent's response shall be determined by Catalent in its sole discretion.

11.5. **Regulatory Communications and Correspondence**. Except as provided in Section 11.4 ("Regulatory Authority Inspections"), any and all other communications from and to the FDA or other Regulatory Authorities related to the Production of the Product at the Facility shall be handled in accordance with the terms and conditions of the Quality Agreement, or as otherwise agreed in writing by Catalent and Client.

11.6. **Regulatory Filings and Maintenance**. Client shall be solely responsible for preparing and submitting to the FDA all documents necessary for the Regulatory Approval of Product including adverse drug experience reports, field alert reports, periodic reports and applications for renewals, variations, supplements and amendments. Catalent shall prepare and maintain all manufacturing files, certificates, authorizations, data and other records that directly pertain to the Production of the Product, as further set forth in the Quality Agreement or as otherwise agreed in writing by Catalent and Client.

11.7. **Records**. Catalent shall maintain the records required by the terms and conditions of the Quality Agreement, or as otherwise agreed to in writing by Catalent and Client in a Project Plan. Catalent agrees that, in response to any complaint, or in the defense by Client of any litigation, hearing, regulatory proceeding or investigation relating to the manufacture of Product, Catalent shall use [***] efforts to make available to Client (during normal business hours and upon reasonable prior written notice) such Catalent employees and records as may be reasonably necessary to permit the effective response to, defense of, or investigation of such matters, subject to appropriate confidentiality protections. Client shall reimburse Catalent for all costs and expenses incurred by Catalent in connection with the performance of Catalent's obligations under the immediately preceding sentence.

11.8. **Notification**. Each Party shall promptly notify the other of new regulatory requirements of which it becomes aware that are relevant to the Production of a Product under this Agreement and that are required by the FDA, any other applicable Regulatory Authority or other Applicable Laws or governmental regulations. The Parties shall confer with each other with respect to the best means to comply with such requirements.

11.9. **Ownership of Regulatory Filings**. Client shall be the sole owner of all regulatory filings and all governmental approvals obtained by Client from any Regulatory Authority with respect to the Product. Notwithstanding the foregoing, and for the avoidance of doubt, all rights in and to Catalent Intellectual Property Rights and Catalent Confidential Information shall remain entirely vested in Catalent.

12. Miscellaneous.

12.1. **Assignment**. Neither Party may assign this Agreement without the prior written consent of the other Party, which consent will not be unreasonably withheld. Notwithstanding the foregoing, either Party may, without the prior consent of the other Party, assign this Agreement to the successor entity in connection with a merger or acquisition, or to an entity acquiring substantially all of the product line or business operations of the assigning Party to which this Agreement pertains, provided that such successor or acquiring entity will expressly assume in writing the obligation to perform in accordance with the terms and conditions of this Agreement. Any purported assignment not in compliance with this Section 12.1 ("Assignment") shall be void.

12.2. **Severability**. If any item or provision of this Agreement shall to any extent be invalid or unenforceable, it shall be severed from this Agreement, and the remainder of this Agreement shall not be affected thereby, and each term and provision of this Agreement shall be valid and shall be enforced to the fullest extent permitted by Applicable Law.

12.3. **Notices**. All notices and other communications under this Agreement shall be in writing and shall be deemed given: (A) when delivered personally or by hand; (B) when delivered by electronic mail (e-mail); (C) when received or refused, if sent by registered or certified mail (return receipt requested), postage prepaid; or (D) when delivered, if sent by express courier service; in each case to the parties at the following addresses (or at such other address for a party as shall be specified by like notice; provided, that notices of a change of address shall be effective only upon receipt thereof):

If to Catalent Bloomington:

Catalent Indiana, LLC
1300 South Patterson Drive
Bloomington, Indiana 47403
Attention: [***]
E-Mail: [***]

With a copy to:

Catalent Pharma Solutions, LLC
14 Schoolhouse Road
Somerset, NJ 08873
Attention: [***]
E-Mail: [***]

If to Client: Catalyst Biosciences, Inc.
611 Gateway Boulevard, Suite 710
South San Francisco, CA 94080
Attention: [***]

12.4. **Governing Law**. The Agreement shall be governed by and construed in accordance with the laws of the state of New York, without regard for its conflict of laws principles.

12.5. **Alternative Dispute Resolution**. Any dispute arising between the Parties in connection with this Agreement shall first be presented to the respective senior executives of the Parties for their consideration and resolution as set forth in Section 12.7 ("Attempts to Amicably Resolve Disputes") below. If such Parties' executives cannot resolve such dispute within [***] days, then such dispute may be submitted by either Party to arbitration by the International Institute for Conflict Prevention and Resolution, 30 E. 33rd Street, 6th Floor, New York, NY 10016 ("CPR") by one arbitrator selected by the Parties. If no agreement on an arbitrator can be reached within [***] days after the CPR offers names of potential arbitrators, then the CPR will choose one arbitrator having reasonable experience in commercial transactions of the type described in this Agreement. The arbitration shall take place in the English language in New York City, New York, in accordance with the CPR administered arbitration rules then in effect, and judgment upon any award rendered in such arbitration will be binding and may be entered in any court having jurisdiction of the matter. The arbitration shall commence within [***] days of the date on which an arbitrator is selected. The arbitrator's decision shall set forth a reasoned basis for any award of damages or finding of liability. The arbitrator shall not have power to award damages in excess of actual compensatory damages and shall not multiply actual damages or award punitive damages. The arbitrator shall award to the prevailing party, if any, its costs and attorneys' fees and expenses reasonably incurred in connection with the arbitration.

12.6. **Entire Agreement**. This Agreement constitutes the entire and exclusive agreement between the Parties with respect to the subject matter hereof and supersedes and cancels all previous discussions, agreements, representations, commitments and writing in respect thereof. No amendment or addition to this

Agreement shall be effective unless reduced to writing and executed by the authorized representatives of the Parties. In the event of a conflict between the provisions of this Agreement and the provisions of any exhibits or attachments hereto, including any Project Plan, the provisions of this Agreement shall govern.

12.7. Attempts to Amicably Resolve Disputes.

12.7.1 To avoid litigation and to resolve any conflicts that arise during the performance of the Services or thereafter, Catalent and Client agree that, prior to the commencement of arbitration by either Party, the Parties shall engage in executive mediation. Either Party may seek executive mediation by delivering a written request for such mediation to the other. Delivery of such request may be made by hand or by electronic mail. The request shall be addressed in accordance with Section 12.3 (“Notices”).

12.7.2 Within [***] business days of the delivery of such request, each Party shall appoint a company executive who is not directly involved in the dispute to meet with the other Party’s company executive for the purpose of resolving the dispute. No later than [***] business days from their appointment, the two executives shall meet to consider the dispute. They may request such information as either deems necessary and may meet jointly or separately with the party representatives involved in the dispute. The two appointed executives shall use [***] efforts to reach a resolution of the dispute.

12.7.3 If a resolution is reached, it shall be reduced to writing and shall be final and binding on the Parties.

12.7.4 If the two executives cannot reach agreement within [***] business days of their initial meeting, unless the two executives agree to additional review time, either Party may thereafter pursue any remedy at law or in equity.

12.8. Waiver. No waiver of any rights shall be effective unless consented to in writing by the Party to be charged and the waiver of any breach or default shall not constitute a waiver of any other right hereunder or any subsequent breach or default.

12.9. **Independent Contractors**. Catalent and Client each acknowledge that they shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture, agency or any type of fiduciary relationship. Neither Catalent nor Client shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior consent of the other Party to do so.

12.10. **Affiliate(s)**. Any licenses granted under this Agreement by Client will be deemed to be granted both to Catalent and Catalent's Affiliate(s). Catalent shall cause its Affiliate(s) involved in the provision of the Services to comply fully with the provisions of this Agreement as though such Affiliate(s) were expressly named as joint obligors hereunder.

12.11. **Counterparts/Facsimile**. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Facsimile signatures shall have the same force and effect as original signatures.

12.12. **Subcontracting**. Catalent may subcontract the performance of the Services to qualified third parties only with Client's prior written consent ("**Permitted Subcontractors**") and provided that (a) Catalent notifies Client of the proposed Permitted Subcontractor and identifies the specific Services to be performed by the proposed Permitted Subcontractor, (b) Client provides written approval, such approval not to be unreasonably withheld, and (c) Catalent ensures the Permitted Subcontractor performs those Services in a manner consistent with the terms and conditions of this Agreement. Catalent shall be responsible for all acts and omissions of its Permitted Subcontractors.

12.13. **Force Majeure**. Neither Party shall be liable for failure to perform its obligations under this Agreement (or for a delay in the performance of such obligations), and neither shall be deemed in breach of its obligations, if such failure or delay is due to Force Majeure. In event of Force Majeure, the Party affected thereby shall use [***] efforts to cure or overcome the same and resume performance of its obligations hereunder. If an event of Force Majeure continues and causes a Party to delay its performance of its obligations for more than [***] days, then the other Party shall have the right upon written notice to terminate this Agreement without any liability to the other Party.

12.14. **Bankruptcy**. All rights and licenses granted under or pursuant to this Agreement by one Party to the other are, for all purposes of Section 365(n) of Title XI of the United States Code ("**Title XI**"), licenses of rights to "intellectual property" as defined in Title XI. If a Party seeks or involuntarily is placed under Title XI and the trustee rejects this Agreement as contemplated under 11 U.S.C. 365(n)(1), the other Party hereby elects, pursuant to Section 365(n) of Title XI, to retain all rights granted to it under this Agreement to the extent permitted by Applicable Law.

12.15. **Exporter of Record**. Catalent shall be the exporter of record for any Product shipped out of the United States. Catalent warrants that all shipments of Product exported from the United States will be made in compliance with all export laws and regulations and all applicable import laws and regulations of the country of importation. Catalent shall be responsible for obtaining any licenses or government authorization(s) necessary for the exportation of Product from the United States, and for ensuring that all domestic and international shipments of Product are made in accordance with all applicable laws and regulations, including but not limited to Department of Transportation and Department of Homeland Security regulations related to transportation of biological agents. Catalent's designated carrier and freight forwarder shall solely be Catalent's agent and shall solely be responsible for preparing and filing any relevant declarations or other documents required for the export. Client shall bear all costs and expenses associated with this Section 12.15 ("Exporter of Record").

12.16. **Importer of Record**. In the event any material or equipment to be supplied by Client, including without limitation Client-Supplied Components and Bulk Drug Substance, is imported into the United States for delivery to Catalent ("**Imported Goods**"), such Imported Goods shall be imported DDP Facility (Incoterms 2010). Catalent shall be deemed to be the "Importer of Record" of such Imported Goods. As the Importer of Record, Catalent shall be responsible for all aspects of the Imported Goods including, without limitation (a) payment of all tariffs, duties, customs, fees, expenses and charges payable in connection with the importation and delivery of the Imported Goods, and (b) keeping all records, documents, correspondence and tracking information required by applicable laws, rules and regulations arising out of or in connection with the importation or delivery of the Imported Goods. Client shall reimburse Catalent for (a).

12.17. **Quality Agreement**. The safety, quality control, and quality assurance aspects of the Services shall be pursuant to the Quality Agreement. In the event of a conflict between the provisions of this Agreement and the provisions of the Quality Agreement, the provisions of this Agreement shall govern.

12.18. **Counterparts**. This Agreement may be executed in one or more counterparts, each of which will be deemed an original but all of which together will constitute one and the same instrument. Any photocopy, facsimile or electronic reproduction of the executed Agreement shall constitute an original.

Certain information identified by bracketed asterisks ([* * *]) has been omitted from this exhibit because it is both not material and would be competitively harmful if publicly disclosed.

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

Catalent Indiana, LLC

By: [***]
Name: [***]
Title: [***]

Catalyst Biosciences, Inc.

By: /s/ Nassim Usman
Name: Nassim Usman, Ph.D.
Title: President & CEO