

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

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

Date of Report (Date of earliest event reported): August 7, 2024



ARDELYX, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

400 Fifth Avenue, Suite 210, Waltham,
Massachusetts

(Address of Principal Executive Offices)

001-36485
(Commission
File Number)

26-1303944
(IRS Employer
Identification Number)

02451

(Zip Code)

Registrant's telephone number, including area code: (510) 745-1700

Former Name or Former Address, if Changed Since Last Report: N/A

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:

- 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, par value \$0.0001	ARDX	The Nasdaq Global Market

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 August 7, 2024, Ardelyx, Inc. (the “Company”) entered into a Commercial Supply Agreement (the “Supply Agreement”) with Catalent Pharma Solutions, LLC (“Catalent”). The Supply Agreement is effective as of July 23, 2024.

The Supply Agreement provides that Catalent will perform tableting, testing, release and bulk packaging of IBSRELA® (“Product”) in accordance with the specifications, target yields, and other terms and conditions set forth in the Supply Agreement.

During the term of the Supply Agreement, the Company has agreed to purchase, and Catalent has agreed to manufacture, a minimum number of batches of Product per contract year, subject to the terms and conditions set forth in the Supply Agreement.

The Company will pay Catalent the agreed upon unit prices for Product, which will be adjusted on an annual basis, beginning January 1, 2025, by an amount equal to the increase in the applicable producer price index. The Company will also pay certain other maintenance fees and expenses as contemplated by the Supply Agreement.

The initial term of the Supply Agreement will continue until December 31, 2028, unless terminated earlier by one of the parties. Thereafter, the Supply Agreement will automatically renew for successive terms of two years until terminated by one of the parties. The Supply Agreement provides for termination by either party due to a material breach by the other party, and certain other extenuating circumstances, in each case after the applicable cure period (if any).

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

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
10.1† 104	<u>Commercial Supply Agreement, dated August 7, 2024 and effective as of July 23, 2024, by and between the Company and Catalent.</u> Cover Page Interactive Data File (embedded within the Inline XBRL document).

† Portions of the exhibit, marked by brackets, have been omitted because the omitted information (i) is not material and (ii) is the type that the Company treats as private or confidential.

SIGNATURES

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

Date: August 12, 2024

ARDELYX, INC.

By: /s/ Justin Renz

Justin Renz

Chief Financial and Operations Officer

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE COMPANY TREATS AS PRIVATE OR CONFIDENTIAL.

COMMERCIAL SUPPLY AGREEMENT

Tenapanor hydrochloride tablets

This Commercial Supply Agreement (together with its Schedule(s), the “**Agreement**”) is made as of this 23rd day of July 2024 (the “**Effective Date**”), by and between Ardelyx, Inc., a Delaware corporation, having a place of business at 400 Fifth Avenue, Suite 210, Waltham, Massachusetts 02451 (“**Client**”), and Catalent Pharma Solutions, LLC, a Delaware limited liability company, having a place of business at 14 Schoolhouse Road, Somerset, New Jersey, 08873 (“**Catalent**”).

RECITALS

- A. Client develops, markets and sells pharmaceutical products;
- B. Catalent is a leading provider of commercial manufacturing and packaging services, for pharmaceutical, biotechnology and consumer healthcare companies;
- C. Client and Catalent are parties to a Development Agreement (as hereinafter defined), pursuant to which Catalent performs development services for the Client, including formulation, development, technology transfer, validation and clinical manufacture of the Product using the API.
- D. Client now desires to have Catalent provide the services set forth in this Agreement (as defined below) in connection with Client’s Product (as defined below), and Catalent desires to provide such services, all pursuant to the terms and conditions in this Agreement.

THEREFORE, in consideration of the circumstances described above and the mutual covenants, terms and conditions set forth below, the Parties agree as follows:

Article 1. DEFINITIONS

The following terms have the following meanings in this Agreement:

- 1.1 “**Acknowledgement**” has the meaning set forth in Section 4.3B.
- 1.2 “**Adverse Supply Event**” has the meaning set forth in Section 6.4.
- 1.3 “**Affiliate(s)**” means, with respect to any Person, any other Person that directly, or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with such Person. For the purposes of this definition, “**control**” (including, with

correlative meanings, “controlled by” and “under common control with”) shall mean possession, directly or indirectly, of the power to direct the management and policies of a Person, whether through the ownership of 50% or more of the voting interests of such Person, through contract, or otherwise.

1.4 “**Agreement**” means this document, including all its Attachments and other appendices (all of which are incorporated by reference) and any amendment to any of the foregoing made in accordance with Section 18.1.

1.5 “**Anti-Corruption Laws**” has the meaning set forth in Section 12.1.

1.6 “**API**” means the compound tenapanor hydrochloride.

1.7 “**Applicable Laws**” means, (i) with respect to Client, all laws, ordinances, rules and regulations, currently in effect or enacted or promulgated during the Term, and as amended from time to time, of each jurisdiction in which API or Product is produced, marketed, distributed, used or sold; and (ii) with respect to Catalent, all laws, ordinances, rules and regulations, currently in effect or enacted or promulgated during the Term, and as amended from time to time, of the jurisdiction in which Catalent Processes Product, and cGMP.

1.8 “**Batch**” means a defined quantity of Product, as agreed by the Parties and set forth on Attachment C, that has been or is being Processed in accordance with the Specifications.

1.9 “**Catalent**” has the meaning set forth in the introductory paragraph, or any successor or permitted assign. Catalent Affiliates may perform Services hereunder in accordance with Section 2.2, in which case all references to “Catalent” shall be deemed to refer to or include such Catalent Affiliate as appropriate.

1.10 “**Catalent Defective Processing**” has the meaning set forth in Section 5.2.

1.11 “**Catalent Indemnitees**” has the meaning set forth in Section 13.2.

1.12 “**Catalent Background IP**” has the meaning set forth in Article 11.

1.13 “**Catalent Inventions**” has the meaning set forth in Article 11.

1.14 “**cGMP**” means current Good Manufacturing Practices promulgated by the Regulatory Authorities in the jurisdictions included in Applicable Laws (as applicable to Client and Catalent respectively). In the United States, this includes 21 C.F.R. Parts 210 and 211, as amended; in Canada, this includes Part C, Division 2 of the *Food and Drug Regulations*; and if applicable, in the European Union, this includes 2003/94/EEC Directive (as supplemented by

Volume 4 of EudraLex published by the European Commission), as amended, if and as implemented and applicable in the relevant constituent country.

1.15 “**Client**” has the meaning set forth in the introductory paragraph, or any successor or permitted assign.

1.16 “**Client Indemnitees**” has the meaning set forth in Section 13.1.

1.17 “**Client Inventions**” has the meaning set forth in Article 11.

1.18 “**Client Background IP**” has the meaning set forth in Article 11.

1.19 “**Client-supplied Materials**” means the material to be supplied by or on behalf of Client to Catalent for Processing, including, without limitation, API, as described in Attachment B, as it may be updated by the Parties from time to time.

1.20 “**Commencement Date**” means, with respect to a Product, the first date upon which Client receives all Regulatory Approvals required for sale in the market in the Territory of such Product Processed by Catalent at the Facility. For the avoidance of doubt, the Commencement Date shall be recorded by way of written document (substantially in the form of Attachment A) within 3 months after the occurrence of the relevant Regulatory Authority approval, signed by both Parties, and attached as Attachment A.

1.21 “**Confidential Information**” has the meaning set forth in Section 10.1.

1.22 “**Contract Year**” means, (i) for the first Contract Year, the partial 12-month period beginning on the Commencement Date and ending on December 31 thereafter (“**Contract Year 1**”) and (ii) following Contract Year 1, each consecutive 12-month period beginning on January 1 and ending on December 31 (“**Contract Year 2**”, “**Contract Year 3**”, etc.).

1.23 “**Defect**” and “**Defective Product**” refer to failure of Product to conform to the Specifications and otherwise meet the warranty set forth in Section 12.1C, as further described in Section 5.2.

1.24 “**Deliver**” or “**Delivery**” means, with respect to a quantity of Product ordered under a Purchase Order, that it has been tendered for delivery by Catalent in accordance with this Agreement and the Quality Agreement. The “scheduled Delivery date” means the requested date set forth in a Purchase Order unless adjusted in accordance with Section 4.3B.

1.25 “**Development Agreement**” means the terms and conditions negotiated by the Parties and first executed on May 12, 2023 in connection with development services being performed by Catalent for Client, together with all Quotations and QARs executed thereunder.

- 1.26 “**Discloser**” has the meaning set forth in Section 10.1.
- 1.27 “**Effective Date**” has the meaning set forth in the introductory paragraph.
- 1.28 “**Exception Notice**” has the meaning set forth in Section 5.2.
- 1.29 “[***] **Supply Failure**” means the occurrence of [***] that collectively result in [***].
- 1.30 “**Facility**” means Catalent’s facility located in Winchester, Kentucky, USA or such other facility qualified by Client and agreed by the Parties in writing where Processing shall occur.
- 1.31 “**Firm Commitment**” has the meaning set forth in Section 4.2.
- 1.32 “**In-Process Materials**” means Client-supplied Materials that are currently in use in Processing by Catalent, including Product prior to the moment of Delivery; for clarity, Client-supplied Materials do not constitute In-Process Materials prior to introduction into the Process, and automatically cease to constitute In-Process Materials upon Delivery of Product.
- 1.33 “**Indemnified Matter**” has the meaning set forth in Section 13.3.
- 1.34 “**Intellectual Property**” means all intellectual property (whether or not patented or patentable), including without limitation, patents, patent applications, know-how, trade secrets, copyrights, trademarks, designs, concepts, technical information, manuals, standard operating procedures, instructions, specifications, processes and data.
- 1.35 “[***] **Defect**” means a Defect in the Product that: (a) was [***] pursuant to [***]; and (b) [***]; and (c) is communicated to Catalent within [***].
- 1.36 “**Licensee**” means a Third Party to whom Client has granted rights to commercialize the API and/or Product(s) in respect of one or more jurisdictions in the Territory, as set forth in Attachment E of this Agreement.
- 1.37 “**Losses**” has the meaning set forth in Section 13.1.
- 1.38 “**Major Regulatory Authority**” means each of the following Regulatory Authorities: FDA (for the USA); MHRA (for the UK); EMA (for the EU); ANVISA (for Brazil), Health Canada (for Canada) and NMPA (for China).
- 1.39 “**Minimum Requirement**” has the meaning set forth in Section 4.1.
- 1.40 “**New Invention**” has the meaning set forth in Article 11.

1.41 “**No-Fault Supply Failure**” means that a Batch is determined to be Defective Product, but the cause of the non-conforming Product cannot be ascertained to be Client-supplied Materials or Catalent Defective Processing.

1.42 “**Party**” means Catalent or Client and, when used in the plural, means Catalent and Client together.

1.43 “**Person**” means an individual, a corporation, a limited liability company, a partnership, an association, a trust, or other type of entity or organization, including a government or a political subdivision or an agency thereof.

1.44 “**Process**” or “**Processing**” means the compounding, filling or tableting, encapsulating, testing, release and bulk packaging (but not secondary or retail packaging) of Client-supplied Materials and Raw Materials into Product by Catalent, in accordance with the Specifications and Batch records and under the terms of this Agreement.

1.45 “**Product**” means the bulk pharmaceutical product containing the API, Processed in accordance with the Specifications.

1.46 “**Product Maintenance Services**” has the meaning set forth in Section 2.6.

1.47 “**Purchase Order**” has the meaning set forth in Section 4.3A.

1.48 “**QAR**” means a written quotation amendment record to a Quotation agreed to and executed by the Parties that details any material change in the details of a Quotation or the assumptions upon which a Quotation is based (including cancellation or postponement by Client of the agreed starting date for Services) that require changes in the pricing and timelines set forth or implied in the Quotation.

1.49 “**Quality Agreement**” has the meaning set forth in Section 9.6.

1.50 “**Quotation**” means a separate written quotation on Catalent’s template agreed by the Parties that defines the scope of Validation Services or other Services to be performed by Catalent for the Product and that includes pricing (including, if appropriate, any applicable payment schedule) and the responsibilities of the Parties with respect to such Services. Each Quotation shall be subject to, and shall be deemed to incorporate by reference, all of the terms and conditions of (i) this Agreement if directed to commercial supply of Product, or (ii) the Development Agreement if directed to technology transfer, Validation Services or other development work, except as set forth in Section 2.1 of this Agreement.

1.51 “**Raw Materials**” means all raw materials, supplies, components, consumables, and packaging, other than the Client-supplied Materials, necessary to Process and ship Product in accordance with the Specifications.

1.52 “**Recall**” means any action: (i) by Client to recover title to or possession of quantities of the Product sold or shipped to Third Parties (including, without limitation, the voluntary withdrawal of Product from the market); (ii) by any Regulatory Authority to detain or destroy any of the Product; or (iii) by either Party to refrain from selling or shipping quantities of the Product to Third Parties which would be subject to a Recall if sold or shipped.

1.53 “**Recipient**” has the meaning set forth in Section 10.1.

1.54 “**Regulatory Approval**” means each approval, permit, Product and/or establishment license, registration or authorization, including each approval pursuant to U.S. Investigational New Drug Applications, New Drug Applications and Abbreviated New Drug Applications (or equivalent non-U.S. filings, such as European marketing authorization applications), as applicable, of a Regulatory Authority that is necessary or advisable in connection with the development, manufacture, testing, use, storage, exportation, importation, transport, promotion, marketing, distribution or sale of API or Product by or on behalf of Client or its Licensees in the Territory.

1.55 “**Regulatory Authority**” means each of the international, national, state, local governmental or other regulatory bodies, agencies, departments, bureaus, authorities, courts, or other entities in the Territory responsible for (A) the regulation (including pricing) of any aspect of the Product, including as applicable the FDA and the DEA, or (B) health, safety or environmental matters generally.

1.56 “**Representatives**” of an entity means such entity’s duly authorized officers, directors, employees, agents, members, accountants, attorneys, consultants or other professional advisors.

1.57 “**Review Period**” has the meaning set forth in Section 5.2.

1.58 “**Rolling Forecast**” has the meaning set forth in Section 4.2.

1.59 “**Services**” means all services to be performed by Catalent pursuant to this Agreement, including without limitation the Processing, Product Maintenance Services and VPP Services.

1.60 “**Specifications**” means the then-current version of the Processing instructions as set forth in the master Batch record and the procedures, requirements, standards, quality control testing and methods, production and control records, and any storage requirements, packaging instructions, shipping requirements and other data, and the scope of services as set forth in the

Facilities' systems for the Product, which includes those Specifications for Raw Materials, API and Product.

1.61 “**Supply Failure**” has the meaning set forth in Section 6.3.

1.62 “**Taxes**” has the meaning set forth in Section 7.6.

1.63 “**Term**” has the meaning set forth in Section 16.1.

1.64 “**Territory**” means (a) the United States of America, including its territories, commonwealths, and possessions, China, including Hong Kong and Macau, and Canada and (b) any other country that the Parties agree in writing to add to this definition of Territory in an amendment to this Agreement, but excluding any country or Person that is designated as the target of any comprehensive sanction, restriction, or embargo administered by the United Nations, the European Union, the United Kingdom, or the United States of America.

1.65 “**Third-Party**” means a Person that is neither a Party nor an Affiliate of a Party.

1.66 “**Unit**” has the meaning set forth on Attachment C.

1.67 “**Unit Pricing**” has the meaning set forth in Section 7.1B.

1.68 “**Validation Services**” has the meaning set forth in Section 2.1.

1.69 “**Vendor**” has the meaning set forth in Section 3.2D.

1.70 “**Virtual Technology**” has the meaning set forth in Section 9.5.

1.71 “**VPP Services**” has the meaning set forth in Section 9.5.

Article 2.
VALIDATION, PROCESSING & RELATED SERVICES

2.1 Validation Services. Catalent shall perform Product technology transfer and Process validation (the “**Validation Services**”), if any, under one or more Quotations or QARs executed by the Parties, which Validation Services (including acceptance and rejection) shall be governed by the Development Agreement. However, any Batches from Validation Services that are (a) accepted by Client under the Development Agreement and (b) released to Client for commercial sale in accordance with the Quality Agreement, shall be governed by this Agreement. Any modified or additional Validation Services will be performed under a Quotation or QAR, as applicable, executed by the Parties and governed by the Development Agreement with any Batches meeting the criteria in the immediately preceding sentence also being governed by this Agreement following release for commercial sale.

2.2 Affiliates. The Parties may mutually elect for Services to be performed by a Catalent Affiliate, in which case all references to “Catalent” herein shall apply to such Affiliate with respect to the applicable Services.

2.3 Supply and Purchase of Product. Catalent shall Process Product and otherwise perform its obligations hereunder in accordance with the Specifications, the Quality Agreement, Applicable Laws, and the terms and conditions of this Agreement.

So long as Client is in compliance with the terms of this Agreement, including but not limited to [***], Catalent will not at any time during the Term [***] without Client’s prior written consent in each case; provided however that (a) [***] and (b) Catalent shall in all cases comply with the confidentiality provisions of this Agreement and Catalent’s own standard operating procedures in respect of segregation of Client Confidential Information and Intellectual Property.

2.4 Product Service Management. Each Party will appoint one of its employees as relationship manager responsible for liaising between the Parties (the “**Product Service Manager**”). The Product Service Managers will meet on a frequency agreed between the Parties to review the status of the business relationship, including without limitation review of key performance indicators such as on-time delivery and right first time, and to manage any issues that have arisen.

2.5 Subcontracting. Catalent shall not subcontract the performance of Services under this Agreement without Client’s prior written consent. Any subcontracting permitted hereunder shall be subject to the following express conditions: (i) such subcontractor shall be duly qualified by Catalent and shall perform the Services in a manner consistent with the terms and conditions of this Agreement, and (ii) Catalent remains liable for the performance of the subcontractor.

2.6 Product Maintenance Services. Catalent shall provide and Client will receive product maintenance services (the “**Product Maintenance Services**”) in exchange for Client’s payment of the Annual Product Maintenance Fee, as set forth in Exhibit C, including the following:

- (a) one audit every other year (as further described in Section 9.4);
- (b) regulatory inspections (as further described in Section 9.3) by a Regulatory Authority that is a Major Regulatory Authority;
- (c) one annual Product review (within the meaning of 21 CFR § 211.180);
- (d) access to document library over and above the Quality Agreement, including additional copies of Batch paperwork or other Batch documentation;
- (e) assistance in preparing Regulatory Approvals in the Territory(ies);
- (f) Product document and sample storage relating to cGMP requirements;
- (g) vendor re-qualification;
- (h) maintenance, updates and storage of master Batch records and audit reports;
- (i) bulk stability (6 months, warehouse conditions); tooling and filter bag maintenance, as applicable; and media fill runs, if applicable.

For clarity, the following services and items are not included in Product Maintenance Services:

- (a) regulatory inspections (as further described in Section 9.3) by a Regulatory Authority that is not a Major Regulatory Authority;
- (b) technology transfer;
- (c) analytical work;
- (d) stability, other than the bulk stability described above;
- (e) Process rework;
- (f) replacement columns (e.g., HPLC or UPLOC as applicable); and
- (g) audits and inspections by Client other than those described in Section 9.4, including those requested by Client to be performed by Third Parties, such as industry groups or accrediting organizations.

2.7 Other Related Services. Catalent shall provide Product-related services, other than Validation Services, Processing or Product Maintenance Services, as either specified in Attachment C or agreed in a Quotation or QAR from time to time. Such a Quotation or QAR shall include the scope and fees for any such Product-related services and be appended to this Agreement or, if directed to development activities, the Development Agreement. The terms and conditions of this Agreement or the Development Agreement as applicable, shall govern and apply to such services.

2.8 Facilities. At no additional cost to Client, throughout the Term, Catalent shall maintain the Facility in good working order as necessary for the Processing of the Product in compliance with all Applicable Laws.

Article 3.
MATERIALS

3.1 Client-supplied Materials.

A. Client shall supply to Catalent for Processing, at Client's cost, Client-supplied Materials in quantities sufficient to meet Client's requirements for Product. Client shall deliver such items and associated certificates of analysis to the Facility no later than 90 days (but not earlier than 120 days) before the scheduled Delivery date. Client shall be responsible at its expense for securing any necessary DEA, export, import, or other licenses, clearances, permits, authorizations, or certifications required by Regulatory Authorities in respect of such supply. Catalent shall use Client-supplied Materials solely for Processing pursuant to this Agreement. Prior to or together with delivery of any Client-supplied Materials, Client shall provide to Catalent a copy of all associated safety data sheets, safe handling instructions, health and environmental information, and any governmental certification or authorization that may be required under Applicable Laws relating to the API and Product, and thereafter shall promptly provide any updates thereto.

B. Catalent shall inspect all Client-supplied Materials received to verify their identity. Unless otherwise expressly required by the Specifications or the Quality Agreement, Catalent shall have no obligation to test Client-supplied Materials to confirm that they meet the applicable Specifications, certificate of analysis or otherwise; but, in the event that Catalent detects a nonconformity with the Specifications, Catalent shall give Client prompt notice of such nonconformity. Catalent shall not be liable for any defect in Client-supplied Materials, or in Product as a result of defective Client-supplied Materials, unless Catalent did not perform the foregoing obligations. Catalent shall follow Client's reasonable written instructions in respect of return or disposal of defective Client-supplied Materials, at Client's cost and risk.

C. Catalent will receive Client-supplied Materials arriving at the Facility in accordance with established Facility procedures, and will handle, store, use and dispose of them in accordance with this Agreement, any safety data sheets, safe handling instructions and health and environmental information associated therewith.

D. Subject to applicable limits on liability in Article 14, Catalent shall bear risk of loss to Client-supplied Materials wasted as a result of (i) Catalent Defective Processing, and (ii) Catalent's gross negligence or willful misconduct. Client shall always retain title to Client-supplied Materials and shall bear the risk of loss of any such Client-supplied Materials other than as set forth in this subsection E. Client shall obtain and maintain insurance for Client-supplied Materials (other than In-Process Materials) while at the Facility and in transit to and from any Facility in accordance with Article 15.

E. Subject to applicable limits on liability in Article 14, the Parties will conduct annual API reconciliations in accordance with Attachment D which includes loss of Client-supplied Materials as a result of (i) Catalent Defective Processing, and (ii) Catalent's gross negligence or willful misconduct.

3.2 Raw Materials; Inventory.

A. Catalent shall be responsible for procuring, inspecting, storing, and releasing adequate Raw Materials as necessary to meet the Firm Commitment, unless otherwise agreed by the Parties in writing.

B. With respect to all Product and Client-supplied Materials, including In-Process Materials (collectively, "**Inventory**"), Catalent will provide Client with monthly inventory reports in the form generated by its electronic inventory management system.

C. Catalent will employ commercially reasonable efforts to use Raw Materials and Client-supplied Materials on a first-to-expire, first-out basis, unless otherwise requested by Client in writing and agreed by Catalent in writing. Catalent shall not use either the Raw Materials or Client-supplied Materials beyond the shelf life required under any Applicable Law. Once annually at mutually agreed times, Catalent shall give Client reasonable access to the Inventory and related records, and to the Personnel that regularly manage such Inventory and records, to permit Client to conduct a physical count of all Inventory in Catalent's possession or control. Catalent will use commercially reasonable efforts to assist Client in obtaining access to any Inventory stored by a subcontractor of Catalent. Catalent will promptly advise Client if it encounters Inventory supply problems, including delays or delivery of non-conforming Raw Materials or Client-supplied Materials. Catalent shall not be liable for any delay in delivery of Product to the extent caused by Catalent's inability to obtain, in a timely manner, a particular Raw Material necessary for Processing, so long as Catalent placed orders for such Raw Materials promptly following receipt of Client's Firm Commitment. In the event that any Raw Material becomes subject to purchase lead time beyond the Firm Commitment time frame, the Parties will negotiate in good faith an appropriate amendment to this Agreement, including Section 4.2. Should any supply problems with Vendors of Raw Materials or Client-supplied Materials arise, the Parties will cooperate in good faith to reduce or eliminate such supply problems.

D. If Client requires a specific supplier, manufacturer or vendor ("**Vendor**") to be used for Raw Material and such Vendor and has not previously been qualified by Catalent for purposes of sourcing such Raw Material, then (i) such Vendor will be identified in the Specifications and (ii) the Raw Materials from such Vendor shall be deemed Client-supplied Materials for purposes of the other Sections of this Agreement. If the cost of the Raw Material from any such Vendor is greater than Catalent's costs for the same raw material of equal quality

from other vendors, Catalent shall add the difference between Catalent's cost of the Raw Material and the Vendor's cost of the Raw Material to the Unit Pricing. Client will be responsible for all costs associated with qualification of any such Vendor that has not been previously qualified by Catalent.

E. In the event of (i) a Specification change for any reason, (ii) obsolescence of any Raw Material ordered for Processing of Client's Product, or (iii) termination or expiration of this Agreement, Client shall bear the cost of any Raw Materials ordered for Processing of Client's Product (including packaging) that are unused for Processing or Product, so long as Catalent purchased such Raw Materials in quantities consistent with Client's most recent Firm Commitment and the vendor/Vendor's minimum purchase obligations.

3.3 Artwork and Labeling. Client shall provide or approve, prior to the procurement of applicable Raw Material, all artwork, advertising and labeling information necessary for Processing, if any. Such artwork, advertising and labeling information is and shall remain the exclusive property of Client, and Client shall be solely responsible for the content thereof. Such artwork, advertising and labeling information or any reproduction thereof may not be used by Catalent in any manner other than performing its obligations hereunder without Client's written consent.

Article 4. PURCHASE ORDERS & FORECASTS

4.1 Minimum Requirement.

A. Obligation. During each Contract Year during the Term, or until such earlier date as Catalent first provides services at the Facility in respect of the API to any Third Party following ANDA approval in accordance with Section 3.1D, Client shall place Purchase Orders for the minimum number of Batches of Product set forth on Attachment C (the "**Minimum Requirement**"), subject to the terms and conditions in this Agreement. If Client does not satisfy the Minimum Requirement obligations during any Contract Year, then within 30 days after the end of such Contract Year, Catalent shall deliver to Client an invoice setting forth its calculation of the difference between (A) the total amount Client would have paid to Catalent based on its Minimum Requirement obligations for such Calendar Year and (B) the total amount Client would have paid to Catalent in respect of all Purchase Orders placed for Delivery in accordance with Section 4.3 during such Contract Year, and Client shall pay such invoice in accordance with Section 7.4. Client's satisfaction of the Minimum Requirement shall be calculated based on Purchase Orders placed, in accordance with Section 4.3, for Batches scheduled for Delivery in the applicable Contract Year, irrespective of whether Catalent timely delivers conforming Product in respect of such Purchase Orders.

B. Suspension. The Minimum Requirement for the then-current Contract Year shall be suspended [***] in the event of: (i) [***] or (ii) [***]. The Minimum Requirement shall be reinstated upon [***].

4.2 Forecast. On or before the 10th day of each calendar month during the Term, beginning at least [***] months prior to the anticipated Commencement Date, Client shall furnish to Catalent a written 12-month rolling forecast of the quantities of Product that Client intends to order from Catalent for delivery during such 12-month period (the “**Rolling Forecast**”). The first [***] months of each Rolling Forecast shall constitute a binding order for the quantities of Product specified in such Rolling Forecast, the “**Firm Commitment**”); and the following [***] months of the Rolling Forecast shall be non-binding, good-faith estimates. If Catalent anticipates any capacity challenges with respect to any portion of the Rolling Forecast, Catalent shall notify Client in writing within [***] after becoming aware of such challenges.

4.3 Purchase Orders.

A. From time to time as provided in this Section 4.3A, Client shall submit to Catalent a binding, non-cancelable purchase order for Product specifying the number of Batches to be Processed, the Batch size (to the extent the Specifications permit Batches of different sizes) and the requested Delivery date for each Batch (each, a “**Purchase Order**”); *provided*, that no Purchase Order may be for less than the quantities set forth in Attachment C. Purchase Orders will be provided at least [***] days in advance of the Delivery date requested in the Purchase Order and shall comply with the terms of this Agreement. Subject to Section 4.3C, Purchase Orders for quantities of Product in excess of the Firm Commitment shall be submitted by Client at least [***] days in advance of the Delivery date requested in the Purchase Order.

B. Promptly following receipt of a Purchase Order, Catalent shall issue a written acknowledgement (each, an “**Acknowledgement**”) that it accepts or rejects such Purchase Order. Subject to this Section 4.3B and Sections 4.4 and 4.5, Catalent shall accept any Purchase Order properly submitted by Client in accordance with this Agreement that is not in excess of the Firm Commitment. Each acceptance Acknowledgement shall either confirm the Delivery date set forth in the Purchase Order or set forth a reasonable alternative Delivery date. The Parties will negotiate in good faith and agree on any requested alternative Delivery date. Agreement by Client to delay a requested Delivery date shall in no event result in a failure on the part of Client to meet its Minimum Requirement. A Purchase Order submitted by Client and not properly rejected by Catalent within [***] will be deemed accepted by Catalent. Subject to subsection 4.3C below, Catalent may reject any Purchase Order in excess of the Firm Commitment or otherwise not given in accordance with this Agreement.

C. Notwithstanding Section 4.3B, Catalent shall use commercially reasonable efforts to supply Client with quantities of Product set forth in a Purchase Order which are up to

20% in excess of the quantities specified in the Firm Commitment, subject to Catalent's other supply commitments and manufacturing, primary packaging, and equipment capacity.

D. In the event of a conflict between the terms of any Purchase Order or Acknowledgement and this Agreement, the terms of this Agreement shall control.

4.4 Catalent's Cancellation of Purchase Orders. If Client refuses or fails to supply conforming Client-supplied Materials prior to the deadline set forth in Section 3.1, then notwithstanding anything in Sections 4.2 and 4.4 to the contrary, Catalent reserves the right to cancel all, or any part of, a Purchase Order upon [***] written notice to Client, and Catalent shall have no further obligation or liability with respect to such Purchase Order, provided that Catalent's right of cancellation shall expire if Client delivers the required Client-supplied Materials during the [***] cancellation notice period. Any cancellation of Purchase Orders in accordance with this Section 4.4 shall not constitute a breach of this Agreement by Catalent [***].

4.5 Client's Modification or Cancellation of Purchase Orders.

A. Client may modify the Delivery date or quantity of Product in a Purchase Order only by submitting a written request to Catalent at least [***] days in advance of the earliest scheduled Delivery date covered by such Purchase Order, subject to the Firm Commitment. Such change to the Purchase Order shall be effective and binding against Catalent only upon the written approval of Catalent, and, notwithstanding any such written approval, Client shall remain responsible for the total quantity of Product subject to the Firm Commitment.

B. Notwithstanding any amount due to Catalent under Section 4.1, and subject to the applicable relief available to Client under this Agreement, if Client fails to place Purchase Orders sufficient to satisfy the Firm Commitment, Client shall pay to Catalent in accordance with Article 7 the Unit Pricing for all Units that would have been Processed if Client had placed Purchase Orders sufficient to satisfy the Firm Commitment.

C. Neither changes to nor postponement of any Batch of Product initiated or caused by Client, nor the payment of the fees described in this Section 4.5, will reduce or in any way affect the Minimum Requirement obligations set forth in Section 4.1. Notwithstanding the foregoing, payments made in accordance with Section 4.5B for Units that would have been Processed if Client had placed Purchase Orders sufficient to satisfy the Firm Commitment will count toward the Minimum Requirement.

4.6 Unplanned Delay of Processing. Catalent shall provide Client with as much advanced notice as practicable if Catalent determines that any Processing will be delayed for any reason. Remedies for such delay shall be as set forth in Section 6.3 (Supply Failure).

Article 5.
TESTING; RELEASE

5.1 Batch Records and Data; Release. Unless otherwise agreed to by the Parties, after Catalent completes Processing of a Batch, Catalent shall provide Client with (i) copies of Batch records, (ii) Catalent's certificate of analysis for such Batch, and (iii) other documents required for release under the Quality Agreement prepared in accordance with the Specifications (collectively, "**Release Documents**"). All Release Documents shall constitute Client Confidential Information. Catalent shall also provide any support documents reasonably requested by Client in connection with a particular release (e.g., manufacturing chart recordings, LIMS data) at Client's cost. Issuance of a certificate of analysis by Catalent constitutes release of the Batch by Catalent to Client. Client shall be responsible for final release of Product (including testing, at its cost) to the market.

5.2 Defects. With respect to each Batch, Client will inspect the Release Documents upon receipt in accordance with its internal quality control procedures. Within [***] days after tender of delivery of a Batch and Client's receipt of the complete and correct Release Documents ("**Review Period**"), Client or its designee shall notify Catalent in writing (an "**Exception Notice**") of any Defects that are identifiable based on the Release Documents (a "**Documentary Exception**"). If Client fails to provide an Exception Notice within the Review Period, the Batch shall be deemed accepted by Client. [***].

5.3 Investigation. Upon timely receipt of an Exception Notice, Catalent shall conduct an appropriate investigation in its discretion to determine (i) whether Catalent agrees with Client that the Batch is Defective Product and (ii) the cause of any nonconformity. If Catalent agrees that the Batch is Defective Product and determines that the cause of the nonconformity is attributable to Catalent's breach of this Agreement or the Quality Agreement, or Catalent's negligence or willful misconduct ("**Catalent Defective Processing**"), then Section 5.6 shall apply. Notwithstanding the foregoing, if the cause of the nonconformity is attributable to defective Client-supplied Materials, it shall be deemed not Catalent Defective Processing.

5.4 Discrepant Results. If the Parties disagree as to whether a Batch is Defective Product or whether the cause of the nonconformity is Catalent Defective Processing, and this disagreement is not resolved within 30 days of the Exception Notice date, then the Parties shall cause a mutually acceptable independent Third-Party laboratory to review records, test data, and perform comparative tests or analyses on samples of the alleged Defective Product and its components, including Client-supplied Materials. The independent Third-Party laboratory's results as to whether or not the Batch is Defective Product and the cause of any nonconformity shall be final and binding. Unless otherwise agreed by the Parties in writing, the costs associated with such testing and review shall be borne by Catalent if Product is Defective Product attributable to Catalent Defective Processing, and by Client in all other circumstances. For

avoidance of doubt, where the cause of nonconformity cannot be determined or assigned, it shall be deemed not to be Catalent Defective Processing and the failed Batch shall constitute a No-Fault Supply Failure.

5.5 Prompt Replacement. Irrespective of whether a failed Batch results from Catalent Defective Processing, Catalent agrees to re-Process or replace each Defective Batch of Product as soon as practicable if so requested by Client, taking into account Catalent's preexisting commitments to other clients, provided that Client provides sufficient quantities of Client-supplied Materials for such activities. Within 10 business days after Client's rejection of any Product as Defective, the Product Service Managers shall confer to determine the timing of such re-Processing or replacement and to align on any logistical details associated therewith.

5.6 Defective Processing. If Catalent agrees with Client or if the independent Third-Party laboratory determines that the Batch is Defective Product and the cause of the nonconformity is attributable to Catalent Defective Processing, [***]. Catalent shall at Client's option, either:

A. re-Process (if re-Processing is permissible under cGMPs) or replace, at Catalent's cost, another Batch of Product as a replacement for any such Batch of Defective Product using Client-supplied Materials provided by Client at Client's cost in sufficient quantities in order for Catalent to complete such re-Processing or replacing (and Client shall be liable to pay for either the Defective Product or the replacement Product, but not both), or

B. credit to Client's account, any payment made by Client for such rejected Batch of Defective Product.

THE OBLIGATIONS OF CATALENT SET FORTH IN THIS ARTICLE 5 (TESTING AND RELEASE), AND, AS MAY BE APPLICABLE, SECTION 3.1E (MATERIALS), SECTION 4.1B (SUSPENSION), SECTION 6.3 (SUPPLY FAILURE) AND SECTION 9.8 (RECALL) SHALL BE CLIENT'S SOLE AND EXCLUSIVE REMEDIES UNDER THIS AGREEMENT FOR DEFECTIVE PRODUCT AND ARE IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, IN RESPECT OF DEFECTIVE PRODUCT.

Article 6. DELIVERY; SUPPLY FAILURE

6.1 Delivery. Catalent shall deliver Product on the scheduled Delivery date, or such earlier date as the Parties may agree if Product is ready for early release. Product shall be delivered ExWorks (Incoterms 2020) the Facility promptly following Catalent's release of Product. Catalent shall segregate and store all Product until Delivery. To the extent not already held by Client, title to Product shall transfer to Client upon Delivery. Client shall qualify a minimum of 2 carriers to ship Product and then designate the priority of such qualified carriers to Catalent. In the event 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 6.1. Catalent shall not be responsible for Product in transit, including procuring any insurance and the cost thereof, any transport fee for Product, or any risk associated with transit or customs delay, storage, or handling.

6.2 Storage Fees; Risk of Loss. If Client fails to take delivery of any Product on any scheduled Delivery date, Catalent shall store such Product and have the right to invoice Client monthly for reasonable administration and storage costs in accordance with the storage fees set forth in Attachment C. When Catalent provides storage services with respect to any quantity of Product, title to and risk of loss of Product shall pass to Client upon transfer to storage.

6.3 Supply Failure.

A. If Catalent fails to Deliver to Client or its designee at least [***] of Product under a Purchase Order within [***] of the scheduled Delivery date, absent an Adverse Supply Event, such failure shall constitute a “**Supply Failure**”). A Supply Failure may result from both non-Delivered Product and Delivered Product that is Defective due to Catalent Defective Processing. If there is a Supply Failure, Client may in its sole discretion do one or more of the following:

(a) [***]; and

(b) Notwithstanding Section 4.1, adjust its [***] as reasonably required by Client to account for the Supply Failure.

B. Following a determination that an Extreme Supply Failure has occurred, in addition to the remedies for a Supply Failure set forth above and the impact on the Minimum Requirement described in Section 4.1B, Catalent will provide a credit to Client in the amount of [***]% of [***] until the Product is Delivered to Client in accordance with this Agreement, up to a maximum amount of [***]% of [***].

6.4 Adverse Supply Events. An “**Adverse Supply Event**” is one or more of the following: (i) Catalent experiences a Force Majeure Event, (ii) Catalent is unable to comply with a change in the Specifications that is required by a Regulatory Agency, or (iii) a Regulatory Authority orders a halt to any further performance of Processing for a Product. If there is an Adverse Supply Event that Catalent does not remediate so that it can perform the Services in accordance with this Agreement within [***] days after the occurrence of the Adverse Supply Event, Client may, (a) cancel any and all outstanding Purchase Orders to the extent fulfillment thereof by Catalent is impacted by the Adverse Supply Event, including its payment obligations for such canceled Purchase Orders, however Client shall remain responsible for any costs and expenses incurred, and all noncancellable commitments made in connection with such cancelled Purchase

Orders, so long as such costs, expenses or commitments were made by Catalent in compliance with this Agreement, the applicable Purchase Order(s) and the vendor's or Vendor's minimum purchase obligations and/or (b) notwithstanding Section 4.1, adjust its [***] for the period beginning [***] from such Adverse Supply Event as reasonably required by Client to account for the Adverse Supply Event and its impact on forecasted market demands.

Article 7.
FEES, PRICING, AND PAYMENTS

7.1 **Fees.** In consideration for Catalent performing services hereunder:

A. Client shall pay Catalent for performance of the Validation Services, if any, as set forth on any Validation Services Quotations. Catalent shall submit an invoice to Client for such fees as set forth in the executed Validation Services Quotation or QAR.

B. For Batches following the successful completion of the Validation Services, Client shall pay Catalent the initial unit price for Product set forth on Attachment C (together with any subsequent updates to pricing, the “**Unit Pricing**”). Catalent shall submit an invoice to Client for such fees upon tender of Delivery of Product as provided in Section 6.1.

C. Client shall pay Catalent (i) the Annual Product Maintenance Fees for Product Maintenance Services, and (ii) [***]. Catalent shall submit an invoice to Client for such fee prorated to account for the period from the Commencement Date until December 31 of that calendar year, and thereafter on or about the 1st day of each Contract Year.

D. **Other Fees.** Client shall pay Catalent for all other fees and expenses of Catalent invoiced to Client and owing in accordance with the terms of this Agreement, including pursuant to Sections 6.2, 9.2, 9.3, and 16.3 hereof. Catalent shall submit an invoice to Client for such fees in accordance with this Agreement, and otherwise as and when appropriate.

7.2 **Unit Pricing Increase.** The Unit Pricing shall be adjusted on an annual basis, effective on January 1 of each Contract Year beginning with Contract Year 2 for all deliveries on or after January 1, upon 60 days' prior written notice from Catalent to Client, to reflect increases in, among other things, labor, utilities, and overhead and shall be in an amount equal to the increase in the Producer Price Index, “Pharmaceutical Preparation Manufacturing” (Series ID: PCU325412325412), not seasonally adjusted, as published by the U.S. Department of Labor, Bureau of Labor Statistics (“**PPI**”). In addition, price increases for Raw Materials (including those Raw Materials referenced in Section 3.2) shall be passed through to Client at the time of such price increase through an adjustment to the Unit Pricing. For clarity, annual PPI increases to Unit Pricing shall not include Raw Materials cost increases already reflected in the Unit Pricing.

7.3 Cost Improvements. During the Term, Catalent and Client agree to jointly develop a program aimed at achieving continuous improvement in the quality of the Product and reducing Processing costs where possible, which may include refinement of manufacturing processes or procedures, identification of new Vendors or changes in the pricing or availability of Third-Party materials. Any changes to the Process resulting from this program (a) shall be subject to the change control requirements in the Quality Agreement and (b) [***]. Such program will not involve capital or other extraordinary costs being incurred by any Party without the prior written consent of both Parties. Cost reductions resulting from this program and the costs to implement any such programs shall be allocated as agreed between Catalent and Client.

7.4 Payment Terms. Client reserves the right to reasonably dispute the accuracy of any invoice presented by Catalent within 10 business days of Client's receipt of such invoice by providing written notice of such dispute to Catalent. The Parties agree to engage in good faith efforts to resolve any disputed invoice. Payment of all amounts on Catalent invoices that are not disputed in good faith is due 30 days following the date that the invoice is submitted electronically to [***]; provided, however, that in the event of an electronic rejection of Catalent's invoice due to the invalidity of the designated email address or other fault on the part of Client's IT or email system, Catalent shall deliver the relevant invoice by other means permitted under Article 17, and payment of all amounts on Catalent invoices that are not disputed in good faith shall be due 30 days after the date the original invoice was submitted electronically to [***]. Client shall make payment in U.S. dollars, and otherwise as directed in the applicable invoice. Notwithstanding anything to the contrary in this Agreement, if at any time any such undisputed payment is not received by Catalent by its due date, then Catalent may, in addition to other remedies available at law or in equity, charge interest on the outstanding sum from the due date (both before and after any judgment) at [***]% per month until paid in full (or, if less, the maximum amount permitted by the governing law of this Agreement), without releasing Client from its obligations under this Agreement or the applicable Quotation. Failure to bill for interest due shall not be a waiver of Catalent's right to charge interest. Catalent shall not suspend Processing, withhold Product, or otherwise delay or stop providing Services in connection with any such good faith dispute.

7.5 Advance Payment. Notwithstanding anything to the contrary in this Agreement, Catalent may require payment in advance or the posting of a letter of credit before performing any further services, including Processing, or making any further shipment of Product if (A) Client has, on 2 or more occasions in any 12-month period, failed to timely pay any invoice or (B) Client has not established an acceptable credit rating or Client's credit rating has been or is likely to be downgraded. If Client shall fail, within a reasonable time, to make such payment in advance or post such letter of credit as required, or if Client shall fail to make any payment when due, Catalent shall have the right, to terminate this Agreement in accordance with Section 16.2B.

7.6 Taxes. All sales, use, gross receipts, compensating, value-added, or other taxes, duties, registrations, tariffs, customs fees, license fees, and other amounts assessed by any tax jurisdiction, U.S. Customs or foreign equivalent, or any other regulatory authority (excluding Catalent's net income and franchise taxes) ("**Taxes**"), on or for Client-supplied Materials, all Services, or Product prior to or upon provision or sale to Catalent or Client, as the case may be, whether assessed on Catalent or Client, are the responsibility of Client, whether paid by Catalent or Client, and either Client shall reimburse Catalent for all such Taxes paid by Catalent or such sums will be added to invoices directed to Client. If any deduction or withholding in respect of Taxes or otherwise is required by law to be made from any of the sums payable hereunder, then to the extent permitted by Applicable Law, Client shall be obliged to pay to Catalent such greater sum as will leave Catalent, after deduction or withholding as is required to be made, with the same amount as it would have been entitled to receive in the absence of any such requirement to make a deduction or withholding.

7.7 Client and Third-Party Expenses. Except as may be expressly provided in this Agreement or covered by Product Maintenance Service fees, Client shall be responsible for 100% of its own and all Third-Party expenses associated with development, Regulatory Approval, and commercialization of Product, including regulatory filings and post-approval marketing studies.

7.8 Development Batches. Each Batch produced under this Agreement including those necessary to support the validation portion of Client's submissions for Regulatory Approvals, will be considered to be a "**Development Batch**" until manufacturing, testing, storage methods and processes have been validated in accordance with industry standards (including, with respect to initial Process validation at the Facility, production of at least 3 consecutive Batches of Product that meet the applicable Specifications). Additionally, the term Development Batch shall include any Batch manufactured following (i) a change in Specifications, or (ii) a scale-up in the manufacturing process to produce greater quantities of Product, until Catalent has manufactured the required number of consecutive Batches of Product meeting the new Specifications. All Development Batches shall be Processed pursuant to Quotations and QARs under the Development Agreement, provided that once released by Catalent following Processing of the minimum number of consecutive Batches that meet the applicable Specifications in accordance with the Quality Agreement, the resulting Product will become subject to the terms and conditions of this Agreement. Client acknowledges and agrees that Catalent does not warrant that any Development Batch will meet the Specifications or achieve any other desired technical outcomes. Catalent and Client shall cooperate in good faith to resolve any problem causing an out-of-Specification Batch.

Article 8.
CHANGES TO SPECIFICATIONS

8.1 All Specifications, and any change to the Specifications agreed by the Parties from time to time, shall be in writing, dated and signed by the Parties, and shall be modified in accordance with the change control process set forth in the Quality Agreement. No change in the Specifications shall be implemented by Catalent, whether requested by Client or requested or required by any Regulatory Authority, until the Parties have agreed in writing to such change, the implementation date of such change, and any increase or decrease in costs, expenses or fees associated with such change (including any change to Unit Pricing). Catalent shall respond promptly to any request made by Client for a change in the Specifications and provide the estimated costs associated with such change, and both Parties shall use commercially reasonable, good-faith efforts to agree to the terms of such change in a timely manner. Catalent agrees that any changes mandated by a Regulatory Authority will be considered and acted upon expeditiously and with due diligence. Client shall pay all costs associated with agreed changes to the Specifications. Catalent reserves the right to postpone effecting changes to the Specifications until such time as the Parties agree to amend the Specifications. Any changes to the Specifications or Process hereunder shall constitute Client Confidential Information.

Article 9.
RECORDS; REGULATORY MATTERS

9.1 Recordkeeping. Catalent shall maintain materially complete and accurate Batch records, laboratory data, reports, and other technical records relating to Processing in accordance with Catalent standard operating procedures and the Quality Agreement. Such information shall be maintained for the minimum period required by Applicable Laws or, if longer, the period set forth in the Quality Agreement (defined below).

9.2 Regulatory Compliance. The Parties may consult each other in relation to regulatory communications relating to the Product, and any such consultations shall be in accordance with the Quality Agreement. To the fullest extent permitted under Applicable Laws, Client shall have sole authority and responsibility for communicating with any Regulatory Authority responsible for granting Regulatory Approval for the Product with regard to (i) the Product or (ii) any such Regulatory Approval, except to the extent of Catalent's authority and obligation to respond to inquiries and inspection requests from Regulatory Authorities not directed to the Product, including without limitation, communications that relate to Catalent's Facility. Catalent shall obtain and maintain all permits and licenses with respect to general Facility operations required by any Regulatory Authority in the jurisdiction in which Catalent Processes Product. Client shall obtain and maintain all other Product related Regulatory Approvals, authorizations, permits and certificates, including those relating to the import, export, use, distribution, and sale of Product and Client-supplied Materials, including those necessary for Catalent to commence Processing. Client shall reimburse Catalent for any payment Catalent is required to make to any Regulatory Authority pursuant to Applicable Laws relating to Catalent's formulation, development, manufacturing, Processing, filling, bulk packaging, storing, or testing of Product

or Client-supplied Materials at the Facility. During the Term, Catalent will assist Client, and if requested by Client, its Affiliates and Licensees, with all regulatory matters relating to Product, at Client's request and subject to Client's reimbursement of Catalent's reasonable and documented out of pocket costs. The Parties shall cooperate to allow each Party to satisfy its obligations under Applicable Laws relating to performance of this Agreement.

9.3 Government/Regulatory Inspections and Requests. Each Party shall promptly advise the other Party of any proposed or actual inspection or inquiry by any Regulatory Authority concerning Client's API, Product or Processing of Client's Product at the Facility, as specified and within the time frame agreed to in the Quality Agreement. To the extent the inspection is announced, Catalent will, to the extent practicable and permitted under Applicable Law, promptly inform Client and permit Client's agents and representatives to be present at the Facility on the date and time of the Regulatory Authority inspection. Client acknowledges that it may not direct the manner in which Catalent fulfills its obligations to permit inspection by and to communicate with Regulatory Authorities. Subject to the foregoing and to the greatest extent permitted under Applicable Law or by the applicable Regulatory Authority, Catalent shall employ commercially reasonable efforts so as to allow Client up to 3 business days to comment on Catalent's proposed plan of action for responding to or complying with any associated demand or request of a Regulatory Authority, consider all Client's reasonable comments in good faith, and provide to Client copies of all documents submitted to the Regulatory Authority (redacted to the extent containing Confidential Information of Catalent or its other customers). For the avoidance of doubt, Catalent will not delay its response to such Regulatory Authority due to Client's review or comment if Catalent reasonably determines that such delay is likely to cause Catalent to violate any deadline set forth by the applicable Regulatory Authority or Applicable Law. In accordance with the time frame agreed to in the Quality Agreement, and as required by the Quality Agreement, Catalent shall provide to Client a copy of any report issued by such Regulatory Authority and received by Catalent following a visit to the Facility concerning the Client's API, Product, or Processing of Client's Product, redacted as appropriate to protect any Confidential Information of Catalent and the confidential information of Catalent's other customers. Client shall provide to Catalent any material correspondence with such Regulatory Authority relating to Product Processed hereunder, including FDA refusal to file, rejection or warning letters. Except as already included in Product Maintenance Services or as otherwise provided in this Agreement, Client shall reimburse Catalent for all reasonable and documented costs associated with inspections by Regulatory Authorities in connection with Client's API, Product, or Processing of Client's Product. Without limiting the foregoing, Client shall promptly notify Catalent of any communication from a Regulatory Authority relating to Processing at the Facility and shall consult Catalent in advance regarding any response to such Regulatory Authority to the extent that such response concerns Processing.

9.4 Client Access to Facility. During the Term, Client's Representatives and Licensees shall be granted access, as mutually agreed in advance by the Parties, at reasonable times during

regular business hours, to (A) the portion of the Facility where Catalent Processes Product or performs other services, (B) relevant personnel involved in Processing or other services, and (C) Processing records described in Section 9.1, in each case solely for the purpose of verifying that Catalent is Processing Product or performing other services in accordance with this Agreement, the applicable Quotation, Applicable Laws, the Specifications and, if applicable, the Product master Batch record. Client may conduct quality assurance Facility audits at the frequency established in the Quality Agreement (or, if no Quality Agreement is in place, every other year). There shall be no cost to Client for audits conducted every other year. Additional audits will be invoiced by Catalent separately at the then-current rate for such audit, unless such audit is “for cause”. Any request for an audit must be provided at least 60 days in advance of the requested audit date unless otherwise agreed to mutually by the Parties or unless the audit is “for cause”, in which case such audit shall take place at a mutually agreeable time or as earlier required in the Quality Agreement. Audits and inspections shall be designed to minimize disruption of operations at the Facility. For any audit or visit conducted by Client or Client's Licensees or Third-Party contractors pursuant to this Section: (1) Client's non-employee Representatives, Licensees and Third-Party contractors who are not contractually bound to obligations of confidentiality consistent with this Agreement may be required to sign Catalent's standard visitor confidentiality agreement prior to being allowed access to the Facility; (2) any participating Licensees, Representatives and Third-Party contractors shall comply with the Facility's rules and procedures; and (3) Client shall indemnify and hold harmless Catalent for any action, activity, or omission of or by any Licensee, Representative or Third-Party contractor to the extent resulting from a material violation of the Facility's rules and procedures while at the Facility.

9.5 Virtual Inspections or Audits. Inspections by Regulatory Authorities under Section 9.3 may be, and Client Facility audits under Section 9.4 may, at the Parties' mutual election, be conducted by live and/or pre-recorded (as may be applicable) video and audio streaming sessions from a Facility using (A) integrated wearable “Smart Glasses” or other technologies employed by Catalent in order to facilitate remote site visits, and/or (B) a set of related applications and software (collectively, the “**Virtual Technology**”) to facilitate telepresence between Facility personnel and Regulatory Authorities or Client (“**VPP Services**”). Catalent has the right to change, modify, add to, or discontinue any feature of the VPP Services at any time, with prior notification to Client. Catalent shall provide access to live video streaming sessions via a web portal URL. Users of the Virtual Technology shall be responsible for maintaining the confidentiality of passwords and for installing anti-virus software and related protections applicable to the Virtual Technology being employed. Client may not record, by any technology or other means, any of the live video streaming sessions, or other data, information, or activities made available via the VPP Services.

9.6 Quality Agreement. Prior to the first Processing of Product under this Agreement, the Parties shall negotiate in good faith and enter into a quality agreement (the “**Quality**

Agreement”). If determined necessary by Catalent and Client, the Parties shall enter into separate Quality Agreements for each Facility. In the event of a conflict between any provision of this Agreement and the Quality Agreement with respect to quality-related activities, including compliance with cGMP, the provisions of the Quality Agreement shall govern. In the event of a conflict between any provision of this Agreement and the Quality Agreement with respect to any other matter, including allocation of risk, liability and financial responsibility, the provisions of this Agreement shall govern.

9.7 Countries Subject to Restrictions. Catalent shall not be obliged to perform any services which would involve any countries that are targeted by the comprehensive sanctions, restrictions or embargoes administered by the United Nations, the European Union, the United Kingdom, or the United States of America. Further, Catalent shall not be obliged to Process Products for sale in any of such targeted country or for sale to any such Person if Catalent is prevented from doing so, or would be required to obtain or apply for special permission to do so, due to any restriction (such as an embargo) imposed on it by any governmental authority, including those imposed by the U.S. Department of the Treasury’s Office of Foreign Assets Control.

9.8 Recall. The Parties will each maintain records necessary to permit a Recall of any Product delivered to Client or its designee in accordance with the terms of the Quality Agreement. If a Regulatory Authority or court of competent jurisdiction orders or requires the recall of Product supplied pursuant to this Agreement or if either Party believes a recall, field alert, Product withdrawal, or field correction (“**Recall**”) may be necessary with respect to Product supplied under this Agreement, the Party receiving the notice from the Regulatory Authority or court, or that holds such belief, shall comply with the Recall process defined in the Quality Agreement. Catalent will cooperate as reasonably required by Client, having regard to all Applicable Laws, provided that the decision to initiate a Recall or to take some other corrective action, if any, will be made and implemented by Client. Catalent shall assist Client’s Pharmacovigilance team in any Product investigation and Recall assessments, and with relevant responses and communications to Regulatory Authorities. The cost of any Recall shall be borne by Client, and Client shall reimburse Catalent for expenses incurred in connection with any Recall, in each case unless such Recall is caused directly and primarily by Catalent’s (i) negligence or willful misconduct or material breach of its obligations under this Agreement, or (ii) violation of Applicable Laws (in either of such cases then such cost shall be borne by Catalent), and provided that neither Client nor any Third-Party (other than Catalent’s Representatives and contractors) bears material contributory responsibility for necessitating such Recall. For purposes hereof, reimbursable costs shall be limited to reasonable, actual and documented administrative costs incurred by Client or Catalent, as applicable, for such Recall and replacement of the Product subject to Recall in accordance with Article 5. In connection with any Recall related to Defective Product, Catalent shall replace such Defective Product in accordance with the terms of Section 5.5 and as applicable Section 5.6.

Article 10.

CONFIDENTIALITY AND NON-USE

10.1 Definition. As used in this Agreement, the term “**Confidential Information**” means all confidential and proprietary information furnished by or on behalf of Catalent or Client (“**Discloser**”), its respective Affiliates or any of its or their respective Representatives, to the other Party (“**Recipient**”), its respective Affiliates or any of its or their respective Representatives in connection with this Agreement, whether furnished before, on, or after the Effective Date and regardless of the form in which it is furnished, including written, verbal, visual, electronic or in any other media or manner and information acquired by observation or otherwise during any site visit at the other Party’s facility, including VPP Services. Confidential Information includes all proprietary technologies, know-how, trade secrets, discoveries, inventions and any other Intellectual Property (whether or not patented), analyses, compilations, business or technical information and other proprietary materials prepared by either Party, their respective Affiliates, or any of its or their respective Representatives, containing or based in whole or in part on any Confidential Information furnished by Discloser, its Affiliates or any of its or their respective Representatives. Confidential Information also includes the existence and terms of this Agreement. Notwithstanding anything to the contrary in this Agreement, the Parties agree that the Specifications, Release Documents and master Batch records for the Product constitute Client Confidential Information.

10.2 Marking. Catalent acknowledges that Client does not desire to receive any Catalent Confidential Information and agrees to use commercially reasonable efforts not to disclose any Catalent Confidential Information to Client except as requested in writing by Client or as expressly contemplated in an executed Quotation or QAR. Catalent further acknowledges that, in accordance with Section 11.4, data and information delivered hereunder will typically constitute Client Confidential Information notwithstanding that such materials may be created by Catalent. [***]. Notwithstanding the foregoing, all information provided by one Party to the other, regardless of being marked or identified as confidential, shall be considered Confidential Information if it would be apparent to a reasonable person familiar with the Discloser’s business and the industry in which it operates that such information belongs to the is of a confidential or proprietary nature.

10.3 Exclusions. Notwithstanding anything to the contrary in Section 10.1, Confidential Information does not include information that (A) is or becomes generally available within the industry to which such information relates other than through a breach of this Agreement, (B) is already known by Recipient at the time of disclosure as evidenced by Recipient’s contemporaneous written records, (C) becomes available to Recipient on a non-confidential basis from a source that is entitled to disclose it on a non-confidential basis, or (D) was or is independently developed by or for Recipient without reference to Confidential Information of Discloser as evidenced by Recipient’s contemporaneous written records; provided, however,

that this Section 10.3 shall not exclude from the definition of Client Confidential Information the Specifications, Release Records, or master Batch records, unless such information is excluded in clause (A) of this Section 10.3.

10.4 Mutual Obligation. Recipient will protect the confidentiality of Discloser's Confidential Information, using such care as it would use for its own Confidential Information of a similar nature, and in no event less than a commercially reasonable degree of care. Recipient will not use Discloser's Confidential Information except in connection with the performance of its obligations and exercise of its rights under this Agreement, and will not disclose, without Discloser's prior written consent, Discloser's Confidential Information to any Third-Party, except that Recipient may disclose Discloser's Confidential Information to any of its Affiliates and its or their respective Representatives (and in the case of Client, to its Licensees), in each case that (A) need to know such Confidential Information for the purpose of performing Recipient's obligations or exercising Recipient's rights under this Agreement, (B) are advised of the contents of this Article, and (C) are bound to Recipient by obligations of confidentiality at least as restrictive as the terms of this Article. Each Party shall be responsible for any breach of this Article by its Affiliates or any of its or their respective Representatives or Licensees, as applicable.

10.5 Permitted Disclosure. Recipient may disclose Discloser's Confidential Information (i) as required in connection with Securities Laws compliance under Section 18.13. With respect to all other disclosures required by Applicable Law, Recipient may disclose Discloser's Confidential Information to the extent required by Applicable Law, *provided*, that, (A) prior to making any such legally required disclosure, Recipient shall give Discloser as much prior notice of the requirement for and contents of such disclosure as is practicable under the circumstances and allowed by Applicable Laws, (B) Recipient shall cooperate with Discloser, at Discloser's request and expense, with any efforts to limit or eliminate such disclosure requirement including any efforts by Discloser to obtain a court order to limit the scope of such disclosure requirement, and (C) Recipient shall make only the minimal disclosure required, including by placing such restriction on the disclosure as may be permitted under the circumstances and the Applicable Laws. Any such disclosure, however, shall not relieve Recipient of its other confidentiality obligations pursuant to this Article unless it results in an exclusion listed in Section 10.3.

10.6 No Implied License. Except as expressly set forth in Section 10.1 or as otherwise expressly set forth in this Agreement, Recipient will obtain no right of any kind relating to, or license under, Discloser's Confidential Information, including no right to file, own, or obtain any patent application or patent, by reason of this Agreement or any performance thereunder. Discloser's Confidential Information will remain Discloser's sole property, subject to Article 11.

10.7 Return of Confidential Information. Upon expiration or termination of this Agreement, Recipient will, and will cause its Affiliates and its and their respective Representatives to, cease use of and, upon written request, within 30 days, either return or destroy (and certify as to such destruction) all of Discloser's Confidential Information, including any copy thereof. Notwithstanding anything to the contrary in the foregoing, (i) the Recipient may retain a single copy of Discloser's Confidential Information for the sole purpose of ensuring compliance with its obligations under this Agreement, and neither Party will be required to destroy Discloser's Confidential Information stored in backed-up computer records, so long as such copies are not readily accessible and are not used or consulted by Recipient for any purpose other than disaster recovery and (ii) Client shall not be obligated to return Catalent Confidential Information that is necessary to the exercise of Client's rights under this Agreement.

10.8 Survival. The obligations of this Article will terminate 5 years from the expiration or termination of this Agreement, except with respect to trade secrets, for which the obligations of this Article will continue for so long as such information remains a trade secret under Applicable Law provided that such trade secrets were clearly marked or identified in writing by Discloser as a "Trade Secret" at the time of disclosure to Recipient hereunder.

Article 11. **INTELLECTUAL PROPERTY**

11.1 Definitions. For purposes hereof:

- A. "**Client Background IP**" means all Intellectual Property and related embodiments owned by or licensed to Client as of the Effective Date, or developed or controlled by Client before or after the Effective Date, other than in connection with this Agreement;
- B. "**Catalent Background IP**" means all Intellectual Property and related embodiments owned by or licensed to Catalent as of the Effective Date or developed or controlled by Catalent before or after the Effective Date; provided, however, that Catalent Background IP does not include (i) any Intellectual Property and related embodiments licensed to Catalent by Client under this Agreement or the Development Agreement or (ii) any Client Inventions developed by Catalent or jointly by the Parties in connection with this Agreement or the Development Agreement;
- C. "**New Invention**" means any Intellectual Property developed by either Party or jointly by the Parties in connection with this Agreement;
- D. "**Client Inventions**" means any New Invention that relates directly and primarily to (i) the Product, including without limitation, developing, formulating,

manufacturing, filling, processing, packaging, analyzing or testing the Product, (ii) Client Background IP or Client's Confidential Information, including without limitation the Process and Specifications or (iii) the API; excluding, for clarity, Catalent Background IP not developed under this Agreement, including softgel fill, shell, or coating related formulations;

- E. "**Catalent Inventions**" means any New Invention, other than a Client Invention, that (i) relates directly and primarily to Catalent Background IP, or (ii) relates to (a) patented Catalent Background IP, (b) developing, formulating, manufacturing, filling, processing, packaging, analyzing or testing pharmaceutical products generally, or (c) softgel fill, shell or coating formulations, excluding, for clarity, any right to the API contained therein.

11.2 [***].

11.3 Ownership of Intellectual Property. All Client Background IP and Client Inventions shall be owned solely by Client and Catalent hereby assigns and agrees to assign to Client all its right, title and interest in and to the Client Inventions. [***]. No right in the foregoing is granted to Catalent under this Agreement, except that Catalent shall have a non-exclusive, royalty-free license to such items solely to the extent necessary to perform its obligations under this Agreement or Quality Agreement executed pursuant to this Agreement. All Catalent Background IP and Catalent Inventions shall be owned solely by Catalent and no right therein is granted to Client under this Agreement [***]. The Parties shall cooperate to achieve the allocation of rights to New Inventions set forth herein. Each Party shall be solely responsible for the costs associated with the protection of its Intellectual Property.

11.4 License of Catalent Background IP and Catalent Inventions. [***]. To the extent the Services require Catalent to incorporate any Catalent Background IP or Catalent Inventions into the Product or Processes related thereto, such use shall be described in writing and agreed by both Parties prior to such incorporation, and Catalent shall grant Client a non-exclusive license under and to all such Catalent Background IP or Catalent Inventions, under mutually agreeable, reasonable commercial terms. [***]. For the avoidance of doubt, no license is granted to any Catalent Background IP or Catalent Inventions used in the Services that is not incorporated into the Product formulation or Process for manufacture.

11.5 Ownership of Data. Except as set forth in Section 11.3, all data and information resulting from the conduct of Services hereunder shall be the sole property of Client and shall be subject to Client's exclusive use, commercial or otherwise.

Article 12.
REPRESENTATIONS AND WARRANTIES

12.1 Catalent. Catalent represents, warrants and undertakes to Client that:

A. Catalent is authorized to enter into this Agreement, and its performance of its obligations under this Agreement or any Quotation or Quality Agreement executed pursuant to this Agreement will not violate Applicable Laws or any contract with any Third-Party;

B. Catalent will not in the performance of its obligations under this Agreement use the services of any Person debarred or suspended under 21 U.S.C. § 335(a) or (b);

C. at the time of Delivery by Catalent as provided in Section 6.1, Product shall have been Processed in accordance with cGMP and all other Applicable Laws and in conformity with the Specifications, and shall not be adulterated, misbranded or mislabeled within the meaning of Applicable Laws; *provided*, that Catalent shall not be liable for defects attributable to Client-supplied Materials (including artwork, advertising and labeling) unless such defect was caused by Catalent's improper handling of Client-supplied Materials;

D. no transaction or dealing under this Agreement shall be conducted with or for any Person or entity that is designated as the target of any comprehensive sanctions, restrictions or embargoes administered by the United Nations, the European Union, the United Kingdom, or the United States of America;

E. Catalent understands that Client may be required to comply with the United States Foreign Corrupt Practices Act, the United Kingdom Bribery Act, and any other Applicable Laws relating to bribery or other corruption activities (collectively, the "**Anti-Corruption Laws**"). Catalent represents and warrants that no one acting on its behalf will give, offer, agree, promise to give, or authorize the giving directly or indirectly, of any money or other quid pro quo as an inducement or reward for favorable action or forbearance from action or the exercise of influence (i) to any governmental official or employee (including employees of government-owned and government-controlled corporations or agencies), (ii) to any political party, official of a political party, or candidate, (iii) to an intermediary for payment to any of the foregoing, or (iv) to any other Person in a corrupt or improper effort to obtain or retain business or any commercial advantage, such as receiving a permit, authorization or license;

F. Catalent has all necessary authority to use, and to permit Client to use, pursuant to this Agreement, all Catalent Background IP; and to Catalent's knowledge, there is no patent or trade secret owned by any Third-Party that would be infringed or misappropriated by Catalent's performance of this Agreement using Catalent Background IP; and [***]; and

G. Catalent has all authorizations, licenses, and permits required by Applicable Laws to perform the Processing at the Facility as contemplated hereunder.

12.2 Client. Client represents, warrants and undertakes to Catalent that:

A. Client is authorized to enter into this Agreement, and its performance of its obligations under this Agreement or any Quotation or Quality Agreement executed pursuant to this Agreement will not violate Applicable Laws or any contract with any Third-Party;

B. Client will not in the performance of its obligations under this Agreement use the services of any Person debarred or suspended under 21 U.S.C. § 335(a) or (b);

C. all Client-supplied Materials shall have been produced and provided to Catalent in accordance with Applicable Laws, shall comply with all applicable specifications, including the Specifications, shall not be adulterated, misbranded, or mislabeled within the meaning of Applicable Laws, and shall have been provided in accordance with the terms and conditions of this Agreement;

D. the content of all artwork, if any, provided by or on behalf of Client to Catalent shall comply with all Applicable Laws;

E. all Product delivered to Client by Catalent shall be held, used, and disposed of by or on behalf of Client in accordance with Applicable Laws, and Client will otherwise comply with Applicable Laws relating to Client's performance under this Agreement;

F. Client will not release to the market any Batch of Product if the required certificates of conformance indicate that Product does not comply with the Specifications or if Client does not hold all necessary Regulatory Approvals to market and sell the Product;

G. Client has all necessary authority, including Intellectual Property rights to use, and to permit Catalent to use in accordance with this Agreement or any Quotation or Quality Agreement executed pursuant to this Agreement, the Client-supplied Materials (including artwork and other Intellectual Property) and Process the Product in accordance with the Specifications;

H. to its knowledge, there is (i) no patent owned by a Third-Party related to the Client Background IP used to Process Product that would be infringed or misused by performance under this Agreement and (ii) no trade secret or other proprietary right of a Third-Party related to the Client Background IP used to Process Product that would be infringed or misappropriated by Catalent's performance under this Agreement;

I. to Client's knowledge following commercially reasonable due diligence, the Services requested by Client to be performed by Catalent under this Agreement will not violate or infringe upon any trademark, tradename, copyright, patent, trade secret, or other Intellectual Property or other right held by any Person or entity;

J. Client has all authorizations, licenses, and permits required by Applicable Laws to deliver (or have delivered) API or other Client- supplied Material to the Facility;

K. no transaction or dealing under this Agreement shall be conducted with or for any Person or entity that is designated as the target of any comprehensive sanctions, restrictions, or embargoes administered by the United Nations, the European Union, the United Kingdom, or the United States of America; and

L. Client understands that Catalent is required to comply with the Anti-Corruption Laws. Client represents and warrants that no one acting on its behalf will give, offer, agree, promise to give, or authorize the giving directly or indirectly, of any money or other quid pro quo as an inducement or reward for favorable action or forbearance from action or the exercise of influence (i) to any governmental official or employee (including employees of government-owned and government-controlled corporations or agencies), (ii) to any political party, official of a political party, or candidate, (iii) to an intermediary for payment to any of the foregoing, or (iv) to any other Person in a corrupt or improper effort to obtain or retain business or any commercial advantage, such as receiving a permit, authorization or license.

12.3 Limitations. THE REPRESENTATIONS AND WARRANTIES SET FORTH IN THIS ARTICLE ARE THE SOLE AND EXCLUSIVE REPRESENTATIONS AND WARRANTIES MADE BY EACH PARTY TO THE OTHER PARTY IN CONNECTION WITH THIS AGREEMENT OR QUALITY AGREEMENT EXECUTED PURSUANT TO THIS AGREEMENT, AND NEITHER PARTY MAKES ANY OTHER REPRESENTATION, WARRANTY, OR GUARANTEE OF ANY KIND WHATSOEVER IN CONNECTION WITH THIS AGREEMENT OR QUALITY AGREEMENT EXECUTED PURSUANT TO THIS AGREEMENT, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY, NON-INFRINGEMENT, OR FITNESS FOR A PARTICULAR PURPOSE.

Article 13. INDEMNIFICATION

13.1 Indemnification by Catalent. Catalent shall indemnify, defend, and hold harmless Client, its Affiliates, and their respective directors, officers, employees, agents, managers, members, and shareholders in their capacities as such (collectively, the “**Client Indemnitees**”) from and against any and all claims, losses, demands, liabilities, damages, costs, and expenses (including reasonable attorneys’ fees and expenses and reasonable investigative costs) incurred by them in connection with any suit, demand, or action by any Third-Party (collectively, “**Loss**”) in connection with, arising out of, or resulting from (A) any breach of Catalent’s representations, warranties, or covenants set forth in this Agreement or any Quotation or Quality Agreement executed pursuant to this Agreement or (B) any gross negligence or willful misconduct by

Catalent; in each case except to the extent that any of the foregoing arises out of or results from any Client Indemnitee's gross negligence, willful misconduct, or breach of this Agreement.

13.2 Indemnification by Client. Client shall indemnify, defend, and hold harmless Catalent, its Affiliates, and their respective directors, officers, employees, agents, managers, members, and shareholders, in their capacities as such (collectively, the "**Catalent Indemnitees**") from and against any and all Loss incurred by them in connection with, arising out of, or resulting from (A) any breach of Client's representations, warranties, or covenants set forth in this Agreement or any Quotation or any Quality Agreement executed pursuant to this Agreement, (B) any manufacture, packaging, sale, promotion, distribution, or use of or exposure to Product or Client-supplied Materials, including product liability or strict liability, (C) Client's exercise of control over the Processing to the extent that Client's written instructions or directions violate Applicable Laws, (D) the conduct of any clinical trial utilizing any material or Product or API, (E) any actual or alleged infringement or violation of any Third-Party patent, trade secret, copyright, trademark, or other proprietary right by any Product, Process, Client-supplied Materials, or Intellectual Property or other information provided or specified by Client, including Confidential Information supplied by or on behalf of Client pursuant to this Agreement, or any Quotation or any Quality Agreement executed pursuant to this Agreement, (F) any gross negligence or willful misconduct by Client or (G) any suit, action, claim or proceeding brought by a Third-Party related to or arising out of the [***].

13.3 Indemnification Procedures. All indemnification obligations set forth in Sections 13.1 and 13.2 are conditioned upon the Person seeking the benefit of such section (A) promptly notifying the indemnifying Party of any suit, action, claim, proceeding, or other liability (each, an "**Indemnified Matter**") of which the Person seeking indemnification becomes aware (including a copy of any complaint, summons, notice, or other instrument related to the Indemnified Matter), *provided, however*, that any failure to provide such notice within a reasonable period shall not relieve the indemnifying Party of its obligations under this Article 13 except to the extent, if any, that the indemnifying Party is actually prejudiced by such failure; (B) allowing the indemnifying Party, if that Party so requests, to conduct and control the defense of any such Indemnified Matter and any related settlement negotiation (at the indemnifying Party's expense), (except that the indemnifying Party (i) must promptly provide and continuously maintain such defense, and (ii) may not settle such Indemnified Matter if such settlement involves the payment of any money by any indemnified Person, any injunction against such indemnified Person, or any admission of liability by such indemnified Person); (C) cooperating with the indemnifying Party upon request in the defense of the Indemnified Matter or any related settlement negotiation (at the indemnifying Party's expense); and (D) not compromising or settling the Indemnified Matter without prior written consent of the indemnifying Party, not to be unreasonably withheld, conditioned, or delayed.

Article 14.
LIMITATIONS OF LIABILITY

14.1 CATALENT'S TOTAL LIABILITY FOR ANY CLAIM UNDER THIS AGREEMENT SHALL IN NO EVENT EXCEED [***].

14.2 CATALENT'S TOTAL LIABILITY UNDER THIS AGREEMENT FOR LOST, DAMAGED, OR DESTROYED CLIENT-SUPPLIED MATERIALS, WHETHER OR NOT SUCH CLIENT-SUPPLIED MATERIALS ARE INCORPORATED INTO PRODUCT [***].

14.3 [***], NEITHER PARTY NOR ITS AFFILIATES SHALL BE LIABLE TO THE OTHER PARTY OR ITS AFFILIATES FOR (A) INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE, OR CONSEQUENTIAL DAMAGES, (B) LOSS OF REVENUES OR PROFITS (WHETHER DIRECT OR INDIRECT), OR (C) LOSS OF DATA, IN EACH CASE ARISING OUT OF PERFORMANCE UNDER THIS AGREEMENT, ANY QUOTATION OR QAR, OR THE QUALITY AGREEMENT EXECUTED PURSUANT TO THIS AGREEMENT, WHETHER IN CONTRACT, IN TORT, OR UNDER STATUTE, EVEN IF SUCH PARTY OR ANY OF ITS AFFILIATES HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING ANYTHING TO THE CONTRARY HEREIN, IN NO EVENT SHALL CATALENT'S LIABILITY UNDER [***].

Article 15.
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 and/or foreign liability insurance with a per-occurrence limit of not less than \$[***] or equivalent and an annual aggregate limit of not less than \$[***] or equivalent; (B) Products and Completed Operations liability insurance with a per-occurrence limit of not less than \$[***] or equivalent covering each Party's own operations arising out of or connecting with this Agreement, providing coverage for bodily injury and property damage claims; (C) employers liability insurance with limits of not less than \$[***] per claim and, if applicable to the jurisdiction, Workers' Compensation insurance with statutory limits. Client shall at its own cost and expense, obtain and maintain All-Risk Property insurance, including transit coverage, in an amount equal to the full replacement value of its property while in, or in transit to or from, the Facility. Catalent shall at its own cost and expense obtain and maintain Manufacturer's Errors and Omissions insurance with limits of not less than \$[***] or equivalent. Client shall obtain a waiver of subrogation clause from its All-Risk Property insurance carrier(s) in favor of Catalent. Each required insurance policy shall be obtained from an insurance carrier with an A.M. Best rating of at least A-VII or equivalent. If any required policy of insurance is written on a claims-made basis, then such policy shall be maintained throughout the Term and for a period of at least [***] thereafter. Each Party shall be

named as an additional insured within the other Party's products liability insurance policies; *provided* that such additional-insured status will apply solely to the extent of the insured Party's indemnity obligations under this Agreement. 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.

Article 16. TERM AND TERMINATION

16.1 Term. This Agreement shall commence on the Effective Date and shall continue until the end of the 5th Contract Year, unless earlier terminated in accordance with Section 16.2 (such term, including any extension in accordance with this Section 16.1, the "**Term**"). Unless this Agreement is terminated in accordance with Section 16.2, the Term shall automatically extend for successive 2-year periods unless and until one Party gives the other Party at least 24 months' prior written notice of its desire to terminate as of the end of the then-current Term.

16.2 Termination Rights.

A. Either Party may terminate this Agreement immediately without further action if the other Party (i) files a petition in bankruptcy, enters into an agreement with its creditors, applies for or consents to the appointment of a receiver, administrative receiver, trustee, or administrator for its affairs, makes an assignment for the benefit of creditors, suffers or permits the entry of any order adjudicating it to be bankrupt or insolvent and such order is not discharged within 30 days, or takes any equivalent or similar action in consequence of debt in any jurisdiction and (ii) as a result of such action, such Party is unable to perform its material obligations hereunder for 30 consecutive days or more. In the event Client takes any action described in (i) above, Catalent reserves the right to immediately require pre-payment for any future Purchase Orders for Product until Client has achieved financial stability to Catalent's satisfaction in Catalent's sole discretion.

B. In the event of a material breach of this Agreement (other than a payment breach), the non-breaching Party shall have the right to terminate this Agreement, but may only do so where the breaching Party fails to cure the breach within [***] after written notice of the breach is given in accordance with Article 17.

C. If Client fails to make payments in accordance with the terms of this Agreement, and such payment breach is not cured within [***] after written notice of non-payment from Catalent, Catalent may terminate this Agreement or (ii) suspend any further performance under

this Agreement until such invoice is paid in full, without releasing Client from its obligations under this Agreement.

16.3 Effect of Termination. Expiration or termination of this Agreement shall be without prejudice to any right or obligation that accrued to the benefit of either Party prior to such expiration or termination. In the event of a termination of this Agreement:

A. Unless otherwise agreed by the Parties, Catalent will use commercially reasonable efforts to terminate all Services in progress in an orderly manner as soon as practical and in accordance with a schedule of Services agreed by both Parties;

B. Catalent shall promptly return to Client or its designee, at Client's expense and direction, any remaining inventory of Product or Client-supplied Materials, and any Raw Materials reflected in the Final Invoice; *provided*, that all outstanding invoices have been paid in full;

C. Within [***] after expiration or the effective date of termination of the Agreement, Catalent shall deliver to Client a final invoice setting forth all Service fees, pass-through expenses and other costs and consideration due by Client (the "**Final Invoice**"). The Final Invoice may include, as applicable, amounts due for any:

- (i) Product that has been Delivered pursuant to Purchase Orders but not yet invoiced,
- (ii) Product Processed pursuant to Purchase Orders that has been completed and released by Catalent but not yet Delivered,
- (iii) in the event that this Agreement is terminated for any reason other than by Client pursuant to Section 16.2A or (B):
 - (a) all Product being Processed pursuant to Purchase Orders (or, alternatively, Client may instruct Catalent to complete such work in process, and the resulting completed Product shall be governed by clause (ii)); and
 - (b) any other costs and expenses incurred, and all noncancellable commitments made, in connection with Catalent's performance of this Agreement, so long as such costs, expenses or commitments were made by Catalent in compliance with this Agreement, Client's most recent Firm Commitment and the vendor's or Vendor's minimum purchase obligations; and

(c) any cost incurred to wind down and cease any ongoing operations in accordance with clause 16.3A.

16.4 Survival. The rights and obligations of the Parties shall continue under Articles 11 (Intellectual Property), 13 (Indemnification), 14 (Limitations of Liability), 17 (Notice), 18 (Miscellaneous); under Articles 10 (Confidentiality and Non-Use) and 15 (Insurance), in each case to the extent expressly stated therein; and under Sections 5.6 (Defective Processing), 7.4 (Payment Terms), 7.6 (Taxes), 7.7 (Client and Third-Party Expenses), 9.1 (Recordkeeping), 9.8 (Recall), 12.1C (Product Warranties), 12.3 (Limitations), 16.3 (Effect of Termination) and 16.4 (Survival), in each case in accordance with their respective terms if applicable, notwithstanding expiration or termination of this Agreement.

Article 17.
NOTICE

17.1 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 e-mailed (*provided* the e-mail is acknowledged by the recipient); (C) when received or refused, if sent by registered or certified mail (return receipt requested), postage prepaid; or (D) when delivered, if sent by a nationally recognized overnight courier service and confirmed delivered by such service; in each case to a Party at the address as set forth with its signature below (or at such other address as a Party shall specify by like notice; *provided*, that notices of a change of address shall be effective only upon receipt thereof).

Article 18.
MISCELLANEOUS

18.1 Entire Agreement; Amendments. This Agreement (including its attachments and exhibits, together with the Quality Agreement constitutes the entire understanding between the Parties, and supersedes any contract, agreement or understanding (oral or written) of the Parties, with respect to its subject matter. For the avoidance of doubt, this Agreement does not supersede the Development Agreement or any existing generally applicable confidentiality agreement between the Parties as it relates to periods prior to the Effective Date or to business dealings not covered by this Agreement. No term of this Agreement may be amended except upon written agreement of both Parties, unless otherwise expressly provided in this Agreement.

18.2 Captions; Certain Conventions. The captions in this Agreement are for convenience only and are not to be interpreted or construed as a substantive part of this Agreement. Unless otherwise expressly provided in this Agreement or the context of this Agreement otherwise requires, (A) words of any gender include each other gender, (B) words such as “herein”, “hereof”, and “hereunder” refer to this Agreement as a whole and not merely to the particular

provision in which such words appear, (C) words using the singular include the plural, and vice versa, (D) the words “include(s)” and “including” shall be deemed to be followed by the phrase “but not limited to”, “without limitation” or words of similar import, (E) the word “or” shall be deemed to include the word “and” (e.g., “and/or”), (F) references to “Article,” “Section,” “subsection,” “clause” or other subdivision, or to an Attachment or other appendix, without reference to a document are to the specified provision or Attachment of this Agreement, and (G) references to “\$” or “dollars” shall be references to the U.S. dollar, unless expressly provided otherwise, (H) subject to Applicable Laws, all references to liabilities or obligations of Catalent shall be subject to Article 14, regardless of whether the particular provision includes a cross-reference to Article 14, and (I) references to any statute or regulation shall be deemed to refer to such statute or regulation as in effect from time to time or any successor statute or regulation, unless expressly provided otherwise. This Agreement shall be construed as if it were drafted jointly by the Parties.

18.3 Further Assurances. The Parties shall execute, acknowledge and deliver such further instruments and take all such other incidental acts as may be reasonably necessary or appropriate to carry out the purpose and intent of this Agreement.

18.4 No Waiver. Failure by either Party to insist upon strict compliance with any term of this Agreement in any one or more instances will not be deemed a waiver of its rights to insist upon such strict compliance with respect to any subsequent failure.

18.5 Severability. If any term of this Agreement is declared invalid or unenforceable by a court or other body of competent jurisdiction, the remaining terms of this Agreement will continue in full force and effect.

18.6 Independent Contractors. The relationship of the Parties is that of independent contractors, and neither Party will incur any debt or make any commitment for the other Party except to the extent expressly provided in this Agreement. Nothing in this Agreement is intended to create or will be construed as creating between the Parties the relationship of joint venturers, partners, employer/employee or principal and agent. Neither Party shall have any responsibility for the hiring, termination or compensation of the other Party’s employees or contractors or for any employee benefit or other employment-related obligation of any such employee or contractor.

18.7 Successors and Assigns. This Agreement will be binding upon and inure to the benefit of the Parties, their successors and permitted assigns. Neither Party may assign this Agreement, in whole or in part, without the prior written consent of the other Party (not to be unreasonably withheld), except that either Party may, without the other Party’s consent (but subject to prior written notice), assign this Agreement in its entirety to an Affiliate or to a successor to substantially all of the business or assets of the assigning Party or the assigning Party’s business

unit responsible for performance under this Agreement and any assignment in violation of this Section 18.7 shall be void *ab initio*.

18.8 No Third-Party Beneficiary. This Agreement shall not confer any right or remedy upon any Person other than the Parties and their respective successors and permitted assigns, except that Client Indemnitees and Catalent Indemnitees may enforce Article 13 of this Agreement to the extent of any indemnifiable Loss.

18.9 Governing Law. This Agreement, and all suits, actions, claims, or proceedings (whether in contract, tort, or statute) that may be based upon, arise out of, or relate to this Agreement, or the negotiation, execution, or performance of this Agreement (including any suit, action, claim, or proceeding, based upon, arising out of, or related to any representation or warranty made in or in connection with this Agreement or as an inducement to enter into this Agreement), shall be governed by, and enforced in accordance with, the internal laws of the State of Delaware, USA, without giving effect to any law, rule, or provision of the State of Delaware, or to any other conflict of law principle, that would cause the application of the laws, rules, or provisions of any jurisdiction other than the State of Delaware. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement.

18.10 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. If such executives cannot resolve such dispute within 90 days of the receipt by one Party of a written notice of demand from the other, the Parties may seek resolution of this dispute in accordance with the preceding paragraph.

18.11 Notwithstanding the foregoing, nothing in this Section 18.10 shall be construed as precluding a Party from bringing an action in a court of competent jurisdiction for interim injunctive relief, which may only be brought prior to the initiation of any such arbitration and only for interim injunctive relief. Once established, the arbitrator shall have the exclusive jurisdiction to consider applications for permanent relief, including permanent injunctive relief.

18.12 No Setoff. Except as expressly provided in this Agreement, each Party (A) shall perform its obligations under this Agreement (including payment obligations) without setoff, deduction, recoupment, or withholding of any kind for amounts owed or payable by the other Party whether under this Agreement, Applicable Law, or otherwise and whether relating to the other Party's breach, bankruptcy, or otherwise, and (B) hereby waives any rights that it may have to such setoff, deduction, recoupment, or withholding of any kind whether such rights arise under this Agreement, Applicable Law, or otherwise.

18.13 Publicity.

A. Neither Party will make any press release or other public disclosure regarding this Agreement or the transactions contemplated hereby without the other Party's express prior written consent, except as required (A) under Applicable Laws, (B) by any governmental agency, or (C) by the securities laws of the United States, or any listing or trading agreement concerning its publicly traded securities, or under any applicable securities laws, or the rules of any stock exchange on which the securities of the disclosing Party are listed (collectively, "**Securities Laws**"); provided in each case that the Party required to make the press release or public disclosure shall use commercially reasonable efforts to obtain the consent of the other Party as to the form, nature, and extent of the press release or public disclosure prior to issuing the press release or making the public disclosure. In addition, neither Party shall use the other Party's name in a manner that could be construed as an endorsement of such Party's products or services, including any scientific conclusion as to safety or efficacy.

B. Notwithstanding the foregoing Section 18.13A, or anything to the contrary in this Agreement, a Party may make disclosures that it believes are required under applicable Securities Laws, based upon the advice of counsel, provided that it shall where reasonably practicable provide the other Party with a copy of the materials proposed to be disclosed and an opportunity to promptly review and comment on the proposed disclosure. To the extent that the other Party reasonably requests that any information in the materials proposed to be disclosed be deleted or redacted, the disclosing Party shall use commercially reasonable efforts to request confidential treatment of such information pursuant to applicable Securities Laws relating to the confidential treatment of information) so that any information that the other Party reasonably requests to be deleted or redacted, to the extent permitted by the applicable government agency, is omitted from such materials.

18.14 Right to Dispose and Settle. Catalent shall not dispose of any Inventory of Product, Client-supplied Materials, equipment, samples or other items belonging to Client, without first using commercially reasonable efforts to obtain instructions from Client in respect of such items. If Catalent is unable to obtain a response from Client within 30 days after making reasonable efforts to do so Catalent may, in its sole discretion to (A) dispose of all such items in accordance with Applicable Law and any safety data sheets, safe handling instructions and health and environmental information provided by Client, and (B) set-off any and all amounts due to Catalent from Client against any credit Client may hold with Catalent. Catalent may also dispose of any Inventory of Product and any Client-supplied Materials, equipment, tools, samples or other items belonging to Client after first seeking instructions from Client per the first sentence of this Section, but without requiring permission from Client, 30 days after expiration or termination of this Agreement, at Client's cost, unless prior written instructions have been provided by Client for returning such materials to Client at Client's cost. For the avoidance of doubt, any disposal by Catalent of Product, Client-supplied Materials, equipment, tools, samples or other items belonging to Client will be carried out in accordance with

Applicable Law and any safety data sheets, safe handling instructions and health and environmental information provided by Client.

18.15 Force Majeure. Except as to payments required under this Agreement, neither Party shall be liable in damages for, nor shall this Agreement be terminable or cancelable by reason of, any delay or default in such Party's performance if such default or delay is caused by events beyond such Party's reasonable control, including acts of God, any action or failure to act of any government or agency thereof occurring after the date of this Agreement, terrorist events, armed hostilities, factory shutdowns, embargoes, wars, or insurrection, riots, civil commotion, labor disturbances, epidemic, destruction of production facilities or materials by earthquakes, fires, floods, or weather, or failure of or shortages due to suppliers, vendors, public utilities, or common carriers; *provided* that the Party seeking relief under this Section 18.14 (a) has taken commercially reasonable measures to avoid, prevent and mitigate against such risks, where possible, (b) shall promptly notify the other Party of such cause(s) beyond such Party's reasonable control, and (c) continues to perform its obligations hereunder to the extent practicable under the circumstances. The Party that invokes this Section 18.14 shall use commercially reasonable efforts to fully reinstate its ongoing obligations to the other Party as soon as practicable. If the cause(s) continue unabated for [***] days, then (i) both Parties shall meet to discuss and negotiate in good faith what modifications to this Agreement should result from such cause(s) and (ii) the Party not seeking relief hereunder shall have a right to [***].

18.16 Counterparts. This Agreement may be executed in one or more counterparts, including by electronic means (e.g., DocuSign or exchange of PDF signature pages), 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.

[Signatures appear on following page]

IN WITNESS WHEREOF, the Parties have caused their respective duly authorized Representatives to execute this Agreement effective as of the Effective Date.

Catalent Pharma Solutions, LLC

/s/ Aris Gennadios

Signature

Aris Gennadios

Printed Name

Group President, Pharma and Consumer Health

Title

Ardelyx, Inc.

/s/ Justin Renz

Signature

Justin Renz

Printed Name

Chief Financial and Operations Officer

Title

Notices to Catalent	Notices to Client
Catalent Pharma Solutions Winchester 1100 Enterprise Drive Winchester, KY 40391 Attn: [***] Email: [***]	Ardelyx, Inc. 400 Fifth Avenue, Suite 210, Waltham, Massachusetts 02451 Attn: [***] Email: [***]
With a copy to: Catalent Pharma Solutions 14 Schoolhouse Road Somerset, NJ 08873 Attn: [***] Email: [***]	With a copy to: Ardelyx, Inc. Attn: [***] Email: [***]

ATTACHMENT A

[To be completed and signed by both Parties and to be attached as Attachment A within three (3) months of the Commencement Date]

The Parties hereby acknowledge and agree that the Commencement Date, as defined in Section 1.19 of the Agreement, is [insert date], which is the date upon which the [insert Regulatory Authority] approved the Product for sale in the market in [insert country/region].

Catalent Pharma Solutions, LLC

Signature

Printed Name

Title

Ardelyx, Inc.

Signature

Printed Name

Title

ATTACHMENT B
CLIENT-SUPPLIED MATERIALS

[**]

ATTACHMENT C
UNIT PRICING AND FEES

[**]

ATTACHMENT D
API RECONCILIATION

[**]

**ATTACHMENT E
LICENSEES OF CLIENT**

[*]**