

**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): December 17, 2022

CATALYST PHARMACEUTICALS, INC.
(Exact Name Of Registrant As Specified In Its Charter)

Delaware
(State or other jurisdiction
of incorporation)

001-33057
(Commission
File Number)

76-0837053
(I.R.S. Employer
Identification No.)

**355 Alhambra Circle
Suite 801
Coral Gables, Florida**
(Address of principal executive offices)

33134
(Zip Code)

Registrant's telephone number, including area code: (305) 420-3200

Not Applicable
Former Name or Former address, if changed since last report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- 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:

<u>Title of Each Class</u>	<u>Name of Exchange on Which Registered</u>	<u>Ticker Symbol</u>
Common Stock, par value \$0.001 per share	NASDAQ Capital Market	CPRX

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 December 17, 2022, Catalyst Pharmaceuticals, Inc. (the “Company”) entered into an Asset Purchase Agreement (the “Purchase Agreement”) with Eisai Co., Ltd (“Eisai”), pursuant to which the Company has agreed to acquire from Eisai the U.S. rights for FYCOMPA® (perampanel) CIII. FYCOMPA® is the first and only non-competitive AMPA receptor antagonist approved for epilepsy. Additionally, Eisai and the Company have entered into an agreement under which the Company has been granted an exclusive option period to review, evaluate and negotiate to acquire a rare epilepsy asset currently in Eisai’s pipeline.

Under the terms of the Purchase Agreement, the Company will pay a \$160 million upfront payment at closing. Additionally, the Company will be obligated to pay a milestone payment in the amount of \$25 million if patent exclusivity for FYCOMPA® is extended by the PTO from May 2025 until June 2026. Finally, after the loss of patent exclusivity for FYCOMPA®, the Company may be obligated to pay certain royalties to Eisai on net sales of FYCOMPA®. The acquisition is structured as an all-cash purchase with no financing contingencies and is expected to be completed during the first quarter of 2023, subject to customary closing conditions and regulatory clearances in the United States. Each of the Company and Eisai have made customary representations, warranties, covenants and indemnities in the Purchase Agreement.

As part of the acquisition transaction, the parties have negotiated and will enter into at the closing of the asset purchase: (i) a short term Transition Services Agreement (the “Transition Services Agreement”) and (ii) a longer term Supply Agreement (the “Supply Agreement”). Under the Transition Services Agreement, a U.S. subsidiary of Eisai will provide commercial and manufacturing services to the Company for a period of 180 days following the closing of the asset purchase (or such longer period as is set forth in the Transition Services Agreement), for which it will be paid service and other amounts in return for such services, all as more particularly set forth in the Transition Services Agreement. Further, under the Supply Agreement, Eisai will manufacture FYCOMPA® for the Company for a period of seven years (or such longer period as is set forth in the Supply Agreement) following the closing of the asset purchase in return for a purchase price for the product determined under the terms of the Supply Agreement.

The foregoing descriptions of the Purchase Agreement, the form of Transition Services Agreement, and the form of Supply Agreement do not purport to be complete and are qualified in their entirety by reference to the full text of such agreements, copies of which are attached as Exhibit 2.1, Exhibit 10.1, and Exhibit 10.2, respectively, to this Form 8-K and are incorporated herein by reference.

Forward-Looking Statements

This Current Report on Form 8-K includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, including statements regarding the timing and ability of the parties to consummate the transaction contemplated by the Purchase Agreement, satisfaction of conditions in connection with the Transaction, the parties’ ability to meet expectations regarding the timing and completion of the transaction and any other statements containing the words “believes,” “expects,” “anticipates,” “plans,” “estimates,” and similar expressions, are forward-looking statements. These forward-looking statements are based on the Company’s current intentions, beliefs and expectations regarding future events. The Company cannot guarantee that any forward-looking statement will be accurate. The reader should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from expectations. The reader is, therefore, cautioned not to place undue reliance on any forward-looking statement. Any forward-looking statement speaks only as of the date of this Form 8-K, and, except as required by law, the Company does not undertake to update any forward-looking statement to reflect new information, events or circumstances.

Item 8.01 Other Events

On December 19, 2022, the Company issued a press release announcing the Purchase Agreement and related transactions. A copy of the press release is attached as **Exhibit 99.1** to this Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

- 2.1* [Asset Purchase Agreement by and between Eisai and the Company, dated as of December 17, 2022 \(certain identified information has been excluded from the exhibit because it both \(i\) is not material and \(ii\) would be competitively harmful if publicly disclosed\).](#)
- 10.1 [Form of Transition Services Agreement between Eisai, Inc., a subsidiary of Eisai, and the Company \(certain identified information has been excluded from the exhibit because it both \(i\) is not material and \(ii\) would be competitively harmful if publicly disclosed\).](#)
- 10.2 [Form of Supply Agreement between Eisai and the Company \(certain identified information has been excluded from the exhibit because it both \(i\) is not material and \(ii\) would be competitively harmful if publicly disclosed\).](#)
- 99.1 [Press release issued by the Company on December 19, 2022](#)
- 104 Cover Page Interactive Data File (embedded within the inline XBRL document)

* Schedules to the Asset Purchase Agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The registrant will furnish copies of any such schedules to the U.S. Securities and Exchange Commission upon request.

SIGNATURES

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

Catalyst Pharmaceuticals, Inc.

By: _____ /s/ Alicia Grande
Alicia Grande
Vice President, Treasurer and CFO

Dated: December 22, 2022

*Certain identified information has been excluded from this exhibit because it is both (i) not material, and (ii) would likely cause competitive harm to the registrant if publicly disclosed. [***] indicates that information has been redacted.*

ASSET PURCHASE AGREEMENT

by and between

EISAI CO., LTD.

and

CATALYST PHARMACEUTICALS, INC.

Dated as of December 17, 2022

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EXHIBITS

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Exhibit B	Buyer FDA Transfer Letter
Exhibit C	Form of Domain Name Assignment Agreement
Exhibit D	Form of Patent Assignment Agreement
Exhibit E	Form of Pharmacovigilance Agreement
Exhibit F	Form of Quality Agreement
Exhibit G	Seller FDA Transfer Letter
Exhibit H	Form of Supply Agreement
Exhibit I	Form of Trademark Assignment Agreement
Exhibit J	Form of Transition Services Agreement

SCHEDULES

Schedule 1.1(a)	Government Contracts
Schedule 1.1(b)	Permitted Encumbrances
Schedule 1.1(c)	Purchased Domain Names
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ASSET PURCHASE AGREEMENT

This Asset Purchase Agreement (this “**Agreement**”) is made and executed as of December 17, 2022, by and between Eisai Co., Ltd., a corporation organized under the laws of Japan (“**Seller**”) and Catalyst Pharmaceuticals, Inc., a Delaware corporation (“**Buyer**”). Seller and Buyer are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**.”

RECITALS

WHEREAS, Seller and certain of its Affiliates are engaged in the Manufacture of the Products for Exploitation in the Territory and the Exploitation of the Products in the Territory (collectively, the “**Product Business**”);

WHEREAS, Seller wishes to sell to Buyer, and Buyer desires to purchase from Seller, certain assets and rights comprising or associated with the Product Business, upon the terms and conditions hereinafter set forth; and

WHEREAS, at the Closing, Seller and Buyer intend to enter into, or cause certain of their respective Affiliates to enter into, the Ancillary Agreements.

NOW, THEREFORE, in consideration of the mutual benefits to be derived from this Agreement and of the representations, warranties, conditions, agreements and promises contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, hereby agree as follows:

ARTICLE 1 DEFINITIONS

1.1 Defined Terms. As used herein, the following terms shall have the following meanings:

“**Accountants**” means an accounting firm of national reputation in the United States (excluding each of Seller’s and its Affiliates and Buyer’s and its Affiliates’ respective regular outside accounting firms) as may be mutually acceptable to Seller and Buyer; *provided, however*, if Seller and Buyer are unable to agree on such accounting firm within 10 days after a need to engage the Accountants arises under this Agreement or any such mutually selected accounting firm is unwilling or unable to serve, then Seller shall deliver to Buyer a list of three other accounting firms of national reputation in the United States that have not performed services for Seller or its Affiliates or Buyer or its Affiliates in the preceding three-year period, and Buyer shall select one of such three accounting firms.

“**Accounts Receivable**” means all accounts receivable, notes receivable and other indebtedness due and owed by any Third Party to Seller or any of its Affiliates arising from sales of any of the Products by or on behalf of Seller or its Affiliates on or prior to the Closing Date.

“**Act**” means the United States Federal Food, Drug and Cosmetic Act.

“**Additional Consideration**” means the aggregate amount of (a) the Milestone Payment and (b) all Royalty Payments.

“**Adverse Event**” means, with respect to a Product, any undesirable, untoward or noxious event or experience associated with the use, or occurring during or following the administration, of such Product in humans, occurring at any dose, whether expected or unexpected and whether or not considered related to or caused by such Product, including such an event or experience as occurs in the course of the use of such Product in professional practice, in a clinical trial, from overdose, whether accidental or intentional, from abuse or misuse, from withdrawal or from a failure of expected pharmacological action of such Product, and including those events or experiences that are required to be reported to the FDA under 21 C.F.R. sections 312.32 or 314.80, as applicable, or to non-U.S. Regulatory Authorities under corresponding applicable Law outside the United States.

“**Affiliate**” means, with respect to a Person, any other Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such first Person. For purposes of this definition, “control” and, with correlative meanings, the terms “controlled by” and “under common control with”, mean (a) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise or (b) the ownership, directly or indirectly, of more than 50% of the voting securities or other ownership interest of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity).

“**Ancillary Agreements**” means the Bill of Sale, the Domain Name Assignment Agreement, the Patent Assignment Agreement, the Pharmacovigilance Agreement, the Quality Agreement, the Trademark Assignment Agreement, the Transition Services Agreement and the Supply Agreement.

“**Antitrust Authorities**” means the United States Federal Trade Commission, the Antitrust Division of the United States Department of Justice, and any non-U.S. competition authorities having jurisdiction over the Transactions under any applicable Foreign Merger Control Law.

“**Antitrust Law**” means the Sherman Antitrust Act of 1890, as amended, the Clayton Act of 1914, as amended, the HSR Act, the Federal Trade Commission Act of 1914, as amended, and all other United States or non-United States, including state, national, or supranational, antitrust, competition or other Laws that are designed or intended to prohibit, restrict or regulate actions having the purpose or effect of monopolization or restraint of trade or lessening of competition through merger or acquisition.

“**Applicable Transition Period**” means [***].

“**Authorization**” means any consent, approval, order, license, permit and other similar authorization of or from any Governmental Authority, together with any renewals, extensions, or modifications thereof and additions thereto.

“**Base Purchase Price**” means \$160,000,000.

“**Bill of Sale**” means the Bill of Sale and Assignment and Assumption Agreement to be entered into by the Parties or their respective Affiliates at Closing, substantially in the form attached as Exhibit A.

“**BPD Fees**” means the fees described in Section 9008 of the Patient Protection and Affordable Care Act, as amended by Section 1404 of the Health Care and Education Reconciliation Act of 2010.

“**Business Day**” means any day other than Saturday, Sunday or a day on which banking institutions in New York, New York are permitted or obligated by Law to remain closed.

“**Buyer FDA Transfer Letter**” means the letter to the FDA in substantially the form attached as Exhibit B, accepting the transfer of rights to the Purchased Regulatory Approvals issued by the FDA from Seller or its applicable Affiliate.

“**Buyer Material Adverse Effect**” means any event, fact, condition, occurrence, change or effect that (a) prevents or materially impedes or materially delays the consummation by Buyer of the Transactions or (b) has, or would reasonably be expected to have, a material adverse impact on Buyer’s and its applicable Affiliates’ ability to perform their respective obligations under this Agreement and the Ancillary Agreements.

“**Buyer Regulatory Approvals and Documentation**” means any and all (a) Regulatory Approvals for the Products in the Territory; (b) documentation comprising such Regulatory Approvals, and (c) data (including clinical and pre-clinical data) contained in any of the foregoing, in each case, that are Controlled by Buyer or any of its Affiliates effective as of and following the Closing and in the format maintained by Buyer or its applicable Affiliates, including, to the extent comprising the foregoing, the Purchased Regulatory Approvals and the Purchased Regulatory Documentation.

“**Buyer Tax Act**” means (a) any election under any provision of applicable Law effective for the Pre-Closing Tax Period that is made after the Closing by Buyer, any of its Affiliates, or any transferee or successor of Buyer or any of its Affiliates and (b) any other action taken, or failure to act, after the Closing and outside of the ordinary course of business, by Buyer, any of its Affiliates, or any transferee or successor of Buyer or any of its Affiliates, in each case, that increases the amount of liability for Taxes with respect to the Product Business or the Purchased Assets for any Pre-Closing Tax Period.

“**Calendar Year**” means each successive period of 12 calendar months commencing on January 1 and ending on December 31; *provided* that the Calendar Year in which Loss of Exclusivity occurs shall begin on the day of Loss of Exclusivity and end on December 31 of such year.

“**cGMP**” means the then-current standards of good manufacturing practice for the manufacture, processing, packaging, testing, holding or distributing of a medicinal product for human use to assure that such medicinal product meets (a) the requirements of applicable Law and other requirements of any applicable Governmental Authority as to safety, identity and strength, and (b) the quality and purity characteristics that it purports or is represented to possess, including as set forth in FDA regulations in 21 C.F.R. Parts 210 and 211.

“**Chargeback Claims**” means chargebacks and other credits and reimbursements (and any associated administrative fees, but excluding Rebates), to customers with respect to a unit of Product sold in the Territory.

“**Closing Date**” means the date on which the Closing occurs.

“**Commercially Reasonable Efforts**” means the performance of obligations or tasks in a sustained manner consistent with the reasonable, diligent and good faith efforts that a reasonable and similarly sized and resourced party in the pharmaceutical industry would normally use for the commercialization of a product having similar technical and regulatory factors and similar market potential, profit potential and strategic value, and that is at a similar stage in its product life cycle, in each case, based on all relevant factors and all conditions then prevailing and without regard to any amounts payable by Buyer or its Affiliates under this Agreement or any Ancillary Agreement.

“**Confidentiality Agreement**” means that certain Mutual Confidential Disclosure Agreement, dated as of June 15, 2022, between Buyer and Seller.

“**Contingent Payment Obligor**” means Buyer, any of its Affiliates, or any of its or their respective transferees, licensees or sublicensees with respect to rights to any Product.

“**Contract**” means any written contract, agreement, license, sublicense, instrument, assignment, purchase order, or other legally binding commitment or arrangement.

“**Control**” means, with respect to any Regulatory Approval, regulatory documentation or regulatory data, Purchased Product Records, Purchased Regulatory Documentation or Intellectual Property Rights, possession of the right, whether directly or indirectly, and whether by ownership, license or otherwise, to assign or grant a license, sublicense or other right to or under such Regulatory Approval, regulatory documentation or regulatory data, Purchased Product Records or Intellectual Property Rights as provided for herein or in any of the Ancillary Agreements without violating the terms of any Contract with any Third Party.

“**Copyright**” means all copyrights, whether or not registered, all copyright registrations and applications therefor and all extensions, restorations, reversions and renewals thereof.

“**COVID-19**” means SARS-CoV-2 or COVID-19, and any evolutions or variants thereof or related or associated epidemics, pandemic or disease outbreaks.

“**COVID-19 Response Action**” means any good faith actions that Seller determines are necessary or prudent to take in connection with the COVID-19 pandemic, such as actions (a) to suspend or resume operation of all or a portion of the facilities Seller, (b) intended to mitigate the adverse effects of such condition on the business, customers, personnel or other stakeholders of Seller or (c) intended to ensure compliance with any Law.

“**Dispute**” means any dispute, controversy or claim (of any and every kind or type, whether based on contract, tort, statute, regulation, or otherwise) arising out of, relating to, or in connection with this Agreement or any Ancillary Agreement or the Transactions, including any dispute as to the construction, validity, interpretation, enforceability or breach of this Agreement or any Ancillary Agreement.

“**Domain Name Assignment Agreement**” means the Domain Name Assignment Agreement to be entered into by Buyer and Seller or such of Seller’s Affiliates which own any of the Purchased Domain Names at Closing, substantially in the form attached as Exhibit C.

“**Encumbrance**” means any mortgage, lien, license, pledge, security interest, or other encumbrance.

“**Excluded Assets**” means [***].

“**Excluded Liabilities**” means [***].

“**Exploit**” means (and, with correlative meanings, the terms “**Exploitation**” and “**Exploiting**”) to import, export, use, have used, sell, offer for sale, have sold, commercialize, hold or keep (whether for disposal or otherwise), transport, distribute, promote or market, but excludes to Manufacture or have Manufactured.

“**FDA**” means the United States Food and Drug Administration and any successor agency thereto.

“**Fundamental Representations**” means those representations and warranties of Seller and Buyer, as applicable, contained in [***].

“**GAAP**” means generally accepted accounting principles, as applied in the United States.

“**Generic Entry**” means the date on which the first Generic Product has been sold and distributed in the Territory for at least three consecutive months.

“**Generic Product**” means, with respect to a Product, any other medicinal product that is approved under 21 U.S.C. 355(b)(2) and for which FDA has determined that such products are therapeutically equivalent, as reflected by an “A” rating in FDA’s Orange Book or 21 U.S.C. 355(j), or in either case any respective successor Law, that identifies in its marketing application such Product as the basis of submission relied on for approval in its application to the FDA. Notwithstanding the foregoing, an “authorized generic drug” within the meaning of Section 505(t) of the Act shall not constitute a Generic Product for purposes of this Agreement.

“**Governmental Authority**” means any supranational, international, nation, commonwealth, province, territory, county, municipality, district, federal, state or local court (or any arbitrator or other tribunal having competent jurisdiction), administrative agency or commission or other governmental authority, instrumentality, domestic or foreign, or any self-regulated organization or quasi-governmental authority.

“**Government Contracts**” means the Contracts listed on Schedule 1.1(a).

“**HSR Act**” means the Hart-Scott-Rodino Antitrust Improvements Act of 1976.

“**IND**” means an Investigational New Drug Application submitted to FDA in accordance with 21 C.F.R. Part 312.

“**Insolvency Event**” means, with respect to any Person (a) the filing in any court or with any other Governmental Authority pursuant to any Law of a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of that Person or of its assets; (b) the proposal of a written agreement for the composition or extension of its debts; (c) being served with an involuntary petition against it, filed in any insolvency or bankruptcy proceeding, and such petition not being dismissed within 60 days after the filing thereof; (d) the consent to the appointment or taking possession by a receiver, liquidator, assignee, custodian, trustee, sequestrator (or similar official) of such Person or for any substantial part of its property or the making of any assignment for the benefit of creditors; (e) any admission by such Person in writing of its inability to pay its debts generally as they become due; (f) the issue or levy of any judgment, writ, warrant of attachment or execution or similar process against a substantial portion of such Person’s property or (g) the sum of such Person’s debts is greater than all of such Person’s property (in each case, at fair value), excluding any property transferred, concealed, or removed with intent to hinder, delay, or defraud such Person’s creditors.

“**Intellectual Property Rights**” means all (a) Patents, (b) Trademarks, (c) Copyrights, (d) Know-How and (e) domain names.

“**Know-How**” means trade secrets, confidential data, technical information, technology, commercially practiced processes, techniques, inventions, assays, know-how and other proprietary information, including specifications, formulations, manufacturing processes, chemical or biological manufacturing control data, quality control and testing procedures, clinical data, and customer and supplier lists.

“**Law**” means any domestic or foreign, federal, state or local statute, law, treaty, judgment, ordinance, rule, administrative interpretation, regulation, order or other requirement having the force and effect of law of any Governmental Authority.

“**Liabilities**” means any debts, liabilities, Losses, claims or complaints of any kind, whether accrued or unaccrued, matured or unmatured, known or unknown, fixed or contingent, determined or determinable, and whether or not the same would be required to be reflected in financial statements or disclosed in the notes thereto.

“**Litigation**” means any action, arbitration, mediation, hearing, proceeding, litigation, suit, warning letter, finding of deficiency or non-compliance, notice of violation or request for recall (whether civil, criminal, administrative, investigative or appellate).

“**Loss**” or “**Losses**” means any losses, damages, judgments, fines, penalties, awards, Taxes, amounts paid in settlement, charges, and reasonable costs and expenses incurred in connection therewith (including costs and expenses in connection with investigations, suits and proceedings, expert fees, accounting fees, advisory fees and reasonable legal fees).

“**Loss of Exclusivity**” means, with respect to a Product, the first date after the Closing Date on which no Valid Claim covers such Product or the Manufacture or Exploitation of such Product in the Territory.

“**Manufacture**” and “**Manufacturing**” means all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, and shipping and holding (prior to distribution) of a pharmaceutical product or any intermediate thereof, including quality assurance and quality control.

“**Manufacturing Know-How**” means [***].

“**Material Adverse Effect**” means an event, fact, condition, occurrence, circumstance, change or effect (“**Effect**”) that, considered either alone or together with all other Effects, is, or would reasonably be expected to be, materially adverse to the business, results of operations or condition (financial or otherwise) of the Product Business, the Purchased Assets and the Assumed Liabilities, taken as a whole; *provided, however*, that, except as provided in the last clause of this definition, none of the following, and no Effects resulting from the following, shall be deemed (individually or in combination) to constitute, or shall be taken into account in determining whether there has been, a “Material Adverse Effect” [***].

“**NDA**” means a New Drug Application, as defined in the Act.

“**NDC**” means “National Drug Code,” which is the ten- or eleven-digit code registered by a company with the FDA with respect to a pharmaceutical product.

“**Net Sales**” means [***].

“**Non-Exclusive IPR**” means [***].

“**Patent Assignment Agreement**” means the Patent Assignment Agreement to be entered into by Buyer and Seller or such of Seller’s Affiliates which own any Purchased Patents at Closing, substantially in the form attached as Exhibit D.

“**Patents**” means patents and patent applications, together with all provisionals, non-provisionals, reissues, continuations, continuations-in-part, divisions, revisions, extensions and reexaminations with respect thereto.

“**Payment Claims**” means BPD Fees, Chargeback Claims, Rebates and all other payment obligations, including for Product returns, allocated between Seller and Buyer (or their respective Affiliates) under Article 3 of the Transition Services Agreement.

“**PDUFA Fees**” means all fees payable with respect to the Products under the Prescription Drug User Fee Act.

“**Permitted Encumbrance**” means any (a) Encumbrance for Taxes not yet due and payable; (b) Encumbrance caused by Law for amounts not material or overdue that does not or would not be reasonably expected to materially detract from the current value of, or materially interfere with, the present use and enjoyment of any Purchased Asset subject thereto or affected thereby in the ordinary course of business of the Product Business; (c) Encumbrance not securing indebtedness or guarantees of indebtedness which does not materially detract from the current value of, or materially interfere with, the present use and enjoyment of such Purchased Asset in the ordinary course of business of the Product Business; (d) right, title or interest of a licensor or

9licensee evident from the face of a license; (e) any Encumbrance disclosed on Schedule 1.1(b); and (f) other imperfections of title, licenses or Encumbrances, if any, that do not materially impair the continued use and operation of the Purchased Assets to which they relate in the conduct of the Product Business.

“**Person**” means any individual, partnership, limited partnership, limited liability company, joint venture, syndicate, sole proprietorship, corporation, unincorporated association, trust, trustee, executor, administrator or other legal personal representative, or any other legal entity, including a Governmental Authority.

“**Pharmacovigilance Agreement**” means the Pharmacovigilance Agreement to be entered into by the Parties or their respective Affiliates at Closing, substantially in the form attached as Exhibit E.

“**Product**” means, as applicable, the pharmaceutical product FYCOMPA® (perampanel) tablets described and approved in NDA #202834 and the pharmaceutical product FYCOMPA® (perampanel) oral suspension described and approved in NDA #208277.

“**Product Labeling**” means, with respect to a Product in the Territory, (a) the Regulatory Authority-approved full prescribing information for such Product, including any required patient information and (b) all labels and other written, printed or graphic matter upon a container, wrapper or any package insert utilized with or for a Product in the Territory (but excluding any Intellectual Property Rights therein).

“**Product Liability Claim**” means any product liability claim asserted by any Third Party with respect to a pharmaceutical product, including any such claim related to any failure to warn or the Manufacture, design, development or use of, or defect in, such product, or any failure of any unit of such product to conform to the applicable specifications therefor.

“**Purchase Price**” means the sum of the Base Purchase Price, the Prorated Prepaid Expenses and any Additional Consideration actually paid.

“**Purchased Copyrights**” means all Copyrights that are owned by Seller or one of its Affiliates as of the Closing that are (a) used as of the Closing Date exclusively in the Exploitation of a Product in the Territory or (b) contained in any of the Purchased Regulatory Documentation or the Purchased Product Records to the extent such Copyrights are exclusive to the Product in the Territory.

“**Purchased Domain Names**” means the domain names listed on Schedule 1.1(c).

“**Purchased Intellectual Property**” means the Purchased Copyrights, the Purchased Domain Names, the Purchased Know-How, the Purchased Patents and the Purchased Trademarks.

“**Purchased Inventory**” means all inventories of finished Product labeled and held for sale in the Territory that are owned by Seller or its relevant Affiliate as of the Closing Date and have not been sold to a Third Party distributor or wholesaler, together with all Product Labeling and packing thereon.

“**Purchased Know-How**” means [***].

“**Purchased Patents**” means the patents listed on Schedule 1.1(d). [***].

“**Purchased Product Records**” means [***].

“**Purchased Regulatory Approvals**” means the Regulatory Approvals listed on Schedule 1.1(e).

“**Purchased Regulatory Documentation**” means [***].

“**Purchased Trademarks**” means the Trademarks listed on Schedule 1.1(f).

“**Quality Agreement**” means the Quality Agreement to be entered into by the Parties or their respective Affiliates at Closing, substantially in the form attached as Exhibit E.

“**Rebates**” means rebates, price reductions or customers, in each case, based on utilization of units of a Product in the United States.

“**Regulatory Approval Holder**” means the holder of a Regulatory Approval for a Product or a Regulatory Approval for any Related Product in accordance with the terms of this Agreement, in each case, in a given jurisdiction outside of the Territory.

“**Regulatory Approvals**” means, with respect to a product, any and all approvals, licenses, price and reimbursement approvals, registrations (except manufacturing establishment registrations) or authorizations of any Governmental Authority in a particular territory necessary to conduct clinical trials for, commercially distribute, sell or market such product in such territory, including, where applicable, (a) NDAs, INDs and FDA’s approval thereof, (b) pre- and post-approval marketing authorizations, (c) labeling approvals, and (d) pricing approvals.

“**Regulatory Authority**” means any Governmental Authority that has jurisdiction over the safety, efficacy, reliability, Manufacture, investigation, sale or marketing of pharmaceutical products, medical products, biologics or biopharmaceuticals, including the FDA.

“**Related Product**” means a product with the same active pharmaceutical ingredient as a Product.

“**Representatives**” means, with respect to any Person, the officers, employees, agents, attorneys, consultants, advisors and other representatives of such Person.

“**Royalty Term**” means the period from the Closing Date to the earlier of (a) the 10th anniversary of the Closing Date and (b) the 1st of January following the first Calendar Year in which the aggregate amount billed or invoiced for sales of the Products by all Contingent Payment Obligors is [***] or less.

“**Seller FDA Transfer Letter**” means the letter to the FDA in the form attached as Exhibit G, transferring the rights to the Purchased Regulatory Approvals issued by the FDA to Buyer.

“**Seller Regulatory Approvals and Documentation**” means [***].

“**Seller’s Knowledge**” means the actual knowledge of the individuals listed on Schedule 1.1(g), assuming reasonable inquiry by such individual of those other employees of the Company who would reasonably be expected to have actual knowledge of the relevant matter based on their duties and responsibilities to the Company.

“**Supply Agreement**” means the Supply Agreement to be entered into by the Parties or their respective Affiliates at Closing, substantially in the form attached as Exhibit H.

“**Tax**” and “**Taxes**” means all taxes of any kind including all U.S. federal, state, local or non-U.S. net income, capital gains, gross income, gross receipt, property, franchise, sales, use, excise, withholding, payroll, employment, social security, worker’s compensation, unemployment, occupation, capital stock, transfer, gains, windfall profits, net worth, asset, transaction and other taxes, and any interest, penalties or additions to tax with respect thereto.

“**Tax Return**” means any return, declaration, report, claim for refund, information return or statement or other document, together with any schedule or attachment thereto and any amendment thereof, that is filed or required to be filed with any Taxing Authority.

“**Taxing Authority**” means any Governmental Authority that imposes, administers, assesses, adjudicates or collects Taxes or Tax Returns.

“**Territory**” means the United States and its territories and possessions.

“**Third Party**” means any Person other than Seller, Buyer and their respective Affiliates and permitted successors and assigns.

“**Trademark**” means any trademark, trade dress, service mark, trade name, brand name, slogan, logo or other designation of origin, whether or not registered, and any registrations and applications for registration thereof, and all renewals thereof, together with all goodwill associated therewith.

“**Trademark Assignment Agreement**” means the Trademark Assignment Agreement to be entered into by Buyer and Seller or such of Seller’s Affiliates which own any Purchased Trademarks at Closing, substantially in the form attached as Exhibit I.

“**Transactions**” means all of the transactions contemplated by this Agreement and each of the Ancillary Agreements.

“**Transferred Contracts**” means the Contracts set forth on Schedule 1.1(h).

“**Transition Services Agreement**” means the Transition Services Agreement to be entered into by the Parties or their respective Affiliates at Closing, substantially in the form attached as Exhibit J.

“**Valid Claim**” means a claim of (a) an issued, in-force, unexpired Patent which claim has not been held invalid or unenforceable by a Governmental Authority of competent jurisdiction from which holding no appeal can be taken or for which the applicable time for appeal has expired, and has not been held to be invalid or unenforceable through re-examination, *inter partes* review, post grant review or disclaimer, opposition procedure, nullity suit, or otherwise, or (b) a pending patent application that has not been finally abandoned, finally rejected, or expired.

The terms set forth below shall have the meanings ascribed thereto in the referenced section:

<u>Term</u>	<u>Section</u>
Actual Prorated Prepaid Expenses	2.3.2(b)
Agreed Amount	7.2.1
Agreement	Preamble
Apportioned Obligations	5.12.1(b)
Assignment	9.7
Assumed Liabilities	2.2.1
Audit Objection Notice	2.5.4(e)
Auditor	2.5.4(d)
Business Employees	5.19.1
Buyer	Preamble
Buyer Confidential Information	5.4.3
Buyer Indemnitees	7.1.1
Buyer Permitted Purpose	5.4.4
Carve-Out Financial Statements	5.11.3
Claim Notice	7.2.2(a)
Closing	2.4.1
Closing Date Payment	2.3.1
Closing Date Prorated Prepaid Expense Statement	2.3.2(b)
Competing Product	5.15
Confidential Information	5.4.1
Confidentiality Period	5.4.3
Controlling Party	7.2.2(b)
Deductible	7.3.1
Disclosing Party	5.4.1
Disclosure Schedules	Article 3
Early Research and Development	5.15

End Date	8.1.2
Enforceability Exceptions	3.1.2
Estimated Prorated Prepaid Expenses	2.3.2(a)
Existing Stock	5.14.1(b)
Final Closing Date Prorated Prepaid Expenses	2.3.2(c)
Financial Information	3.1.12
Foreign Merger Control Laws	4.5.1
fraud	7.5
Indemnification Certificate	7.2.1
Indemnified Party	7.2.1
Indemnifying Party	7.2.1
Milestone Event	2.5.1(a)
Milestone Payment	2.5.1(a)
Net Sales Information	2.5.4(d)
Net Sales Report	2.5.4(a)
Non-Controlling Party	7.2.2(b)
Notice	9.2.1
Objection Notice	7.2.1
Party(ies)	Preamble
Post-Closing Tax Period	5.12.1(b)
Pre-Closing Period	4.1.1
Pre-Closing Tax Period	5.12.1(b)
Product Business	Recitals
Prorated Prepaid Expense Statement	2.3.2(a)
Prorated Prepaid Expense Statement Objection Notice	2.3.2(c)
Prorated Prepaid Expenses	2.3.2(a)
Purchased Assets	2.1.1
Quality Standards	5.14.2(b)
Receiving Party	5.4.1
Registered IP	3.1.11(b)
Retained Names and Marks	5.14.1(a)
Review Period	2.3.2(c)
Royalty Payments	2.5.3(a)

Schedule Supplement	4.2
Seller	Preamble
Seller Confidential Information	5.4.4
Seller Indemnitees	7.1.2
Seller Permitted Purpose	5.4.3
Supplied Product	5.14.1(c)
Third Party Claim	7.2.2(a)
Transfer Taxes	5.12.1(a)
Willful Breach	8.2.2

1.2 Construction. Except where the context otherwise requires, wherever used, the singular includes the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word “or” is used in the inclusive sense (and/or). The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The terms “including” and “include” and variations thereof shall not be deemed to be terms of limitation, but rather shall be deemed to be followed by the words “without limitation.” The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against any Party. If any action is required to be taken by any Party pursuant to this Agreement on a day that is not a Business Day, such action will be required to be taken on the next Business Day following such day. No parol evidence will be introduced in the construction or interpretation of this Agreement unless the ambiguity or uncertainty in issue is plainly discernible from a reading of this Agreement without consideration of any extrinsic evidence. The doctrine of election of remedies will not apply in constructing or interpreting the remedies provisions of this Agreement or the equitable power of a court considering this Agreement or the Transactions. The contents of the Schedules and Exhibits form an integral part of this Agreement and shall have as full effect as if they were incorporated in the body of this Agreement and any reference to “this Agreement” shall be deemed to include the Schedules and Exhibits. No prior draft of this Agreement nor any course of performance or course of dealing will be used in the interpretation or construction hereof. Unless otherwise specified or where the context otherwise requires, (a) references in this Agreement to any Article, Section, Schedule or Exhibit are references to such Article, Section, Schedule or Exhibit of this Agreement; (b) references in any Section to any clause are references to such clause of such Section; (c) “hereof,” “hereto,” “hereby,” “herein” and “hereunder” and words of similar import when used in this Agreement refer to this Agreement as a whole and not to any particular provision of this Agreement; (d) references to a Person are also to its permitted successors and assigns; (e) references to a Law include any amendment or modification to such Law and any rules, regulations or legally binding guidelines issued thereunder, in each case, as in effect at the relevant time of reference thereto; (f) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently amended, replaced or supplemented from time to time, as so amended, replaced or supplemented and in effect at the relevant time of reference thereto; (g) “extent” in the phrase “to the extent” means the degree to which a subject or other thing extends, and such phrase does not mean simply “if”; and (h) references to monetary amounts are denominated in U.S. dollars.

ARTICLE 2
SALE AND PURCHASE OF ASSETS; LIABILITIES

2.1 Sale of Purchased Assets.

2.1.1 Purchase and Sale of Purchased Assets. Upon the terms and subject to the conditions of this Agreement, at and effective as of the Closing, Seller shall (or shall cause its applicable Affiliates to) sell, transfer, convey, assign and deliver to Buyer (or one or more of its Affiliates), and Buyer (or one or more of its Affiliates) shall purchase and accept from Seller (or its applicable Affiliates), all of Seller's (or its applicable Affiliate's) rights, title and interests in, to and under the following (collectively, the "**Purchased Assets**"), free and clear of all Encumbrances (other than Permitted Encumbrances):

- (a) all Purchased Regulatory Approvals; *provided*, that the INDs comprised within the Purchased Regulatory Approvals shall transfer in accordance with the terms of the Transition Services Agreement;
- (b) all Purchased Regulatory Documentation;
- (c) all Purchased Product Records;
- (d) all Purchased Intellectual Property; *provided*, that the Purchased Intellectual Property that comprises Manufacturing Know-How shall be disclosed to Buyer in accordance with the terms of the Supply Agreement;
- (e) all Purchased Inventory; and
- (f) all rights, claims or causes of action with respect to any Litigation available to or being pursued by Seller or its Affiliates against a Third Party to the extent related to the Assumed Liabilities.

2.1.2 Licenses.

(a) Effective as of the Closing Date, Seller, on behalf of itself, its Affiliates and its and their respective transferees, successors and assigns, hereby grants to Buyer and its Affiliates a non-exclusive, irrevocable, perpetual, royalty-free, fully paid-up, non-transferable (except as provided in Section 9.7) license under the Non-Exclusive IPR and, to the extent not included in the Non-Exclusive IPR or the Purchased Know-How, the Manufacturing Know-How, with the right to grant further licenses and sublicenses (through multiple tiers), in each case, to the use by Buyer or any of its Affiliates of such Non-Exclusive IPR and Manufacturing Know-How solely with, and solely to the extent necessary for the conduct of the Product Business. The Parties acknowledge that the Manufacturing Know-How not included in the Purchased Know-How will be disclosed in accordance with the terms of the Supply Agreement.

(b) Effective as of the Closing Date, Buyer, on behalf of itself, its Affiliates and its and their respective transferees, successors and assigns, hereby grants to Seller and its Affiliates a perpetual, irrevocable, worldwide, royalty-free, fully paid-up, non-transferable (except as provided in Section 9.7) right and license (with a right to grant sublicenses through multiple tiers) under the Purchased Patents solely to the extent necessary to (i) Manufacture worldwide the Products under the Transition Services Agreement and the Supply Agreement, which right and license shall be non-exclusive and (ii) Manufacture worldwide the Products or any Related Product solely for Exploitation outside of the Territory, which right and license shall be exclusive (even as to Buyer and its Affiliates).

2.1.3 Excluded Assets. Notwithstanding anything to the contrary in Section 2.1.1, except for the transfer of certain Manufacturing records in accordance with the terms of the Supply Agreement, neither Buyer nor any of its Affiliates shall acquire, pursuant to this Agreement or any Ancillary Agreement, the Excluded Assets, and the Purchased Assets shall not include, and Seller or its Affiliates shall retain following the Closing Date, the Excluded Assets.

2.2 Liabilities.

2.2.1 Assumed Liabilities. Upon the terms and subject to the conditions of this Agreement, at the Closing, Seller or its applicable Affiliates shall assign and Buyer or its applicable Affiliates shall assume and agree to pay and discharge when due [***] ((a) through (d), collectively, the “**Assumed Liabilities**”) [***].

2.2.2 Excluded Liabilities. Notwithstanding anything to the contrary herein, neither Buyer nor any of its Affiliates shall assume any Excluded Liabilities and the Excluded Liabilities shall remain the sole obligation and responsibility of Seller and its Affiliates.

2.3 Consideration.

2.3.1 Closing Date Payment. In consideration of the conveyances contemplated under Section 2.1 and the license grant under Section 2.1.2(a), Buyer shall pay to Seller on the Closing Date, the sum of (a) the Base Purchase Price plus (b) the Prorated Prepaid Expenses ((a) and (b), collectively, the “**Closing Date Payment**”), in each case, by wire transfer of immediately available funds to the account designated by Seller by written notice provided to Buyer not Less than three Business Days prior to the Closing Date.

2.3.2 Prorated Prepaid Expenses.

(a) Not less than three Business Days prior to the Closing Date, Seller shall prepare and provide to Buyer a statement in accordance with Schedule 2.3.2(a) calculating in reasonable detail the amount of costs and expenses attributable to the Exploitation of the Products in the Territory that were paid by Seller or any of its Affiliates prior to the Closing Date for post-Closing periods (“the “**Prorated Prepaid Expense Statement**”), including the portion of the PDUFA Fee payable with respect to the Products for the period from the Closing Date through September 30, 2023 (collectively, “**Prorated Prepaid Expenses**” and such amount, the “**Estimated Prorated Prepaid Expenses**”).

(b) As soon as practicable, but in no event later than 60 days, following the Closing Date, Seller shall cause to be prepared and delivered to Buyer a statement calculating in reasonable detail the actual Prorated Prepaid Expenses as of the Closing Date in accordance with Schedule 2.3.2(a) (the “**Actual Prorated Prepaid Expenses**”), together with reasonable supporting written documentation (the “**Closing Date Prorated Prepaid Expense Statement**”).

(c) Buyer shall have 30 days from the date on which the Closing Date Prorated Prepaid Expense Statement is delivered by Seller to review the Closing Date Prorated Prepaid Expense Statement (the “**Review Period**”). The Closing Date Prorated Prepaid Expense Statement (and the amount of Prorated Prepaid Expenses contained therein) shall become final and binding upon Seller and Buyer at the end of the Review Period, unless Buyer objects to the calculation of Actual Prorated Prepaid Expenses, in which case Buyer shall send written notice (the “**Prorated Prepaid Expense Statement Objection Notice**”) to Seller within such Review Period, setting forth in specific detail the basis for its objection and Buyer’s proposal for any adjustments to the Closing Date Prorated Prepaid Expense Statement. If a timely Prorated Prepaid Expense Statement Objection Notice is delivered to Seller, then the Closing Date Prorated Prepaid Expense Statement (and the Actual Prorated Prepaid Expenses contained therein) shall become final and binding (except as provided below with respect to resolution of disputes) on Seller and Buyer on the first to occur of (i) the date on which Seller and Buyer resolve in writing any differences they have with respect to the matters specified in the Prorated Prepaid Expense Statement Objection Notice and (ii) the date on which all matters in dispute are finally resolved in writing by the Accountants, in each case as provided below. Seller and Buyer shall seek in good faith to reach agreement as to any such proposed adjustment or that no such adjustment is necessary within 15 days following delivery of the Prorated Prepaid Expense Statement Objection Notice. If agreement is reached in writing within such 15-day period as to all proposed adjustments, or that no adjustments are necessary, Seller and Buyer shall revise the Closing Date Prorated Prepaid Expense Statement accordingly. If Seller and Buyer are unable to reach agreement within 15 days following delivery of the Prorated Prepaid Expense Statement Objection Notice, then the Accountants shall be engaged at that time to review the Closing Date Prorated Prepaid Expense Statement, and shall make a determination as to the resolution of any adjustments. The Accountants shall be instructed, pursuant to an engagement letter, to resolve only those matters set forth in the Prorated Prepaid Expense Statement Objection Notice remaining in dispute and not to otherwise investigate any matter independently and to act as an expert and not arbitrator. Buyer and Seller each agree to furnish to the Accountants such individuals and such information, books and records as may be reasonably required by the Accountants to make its final determination. With respect to each disputed item, the Accountants’ decision, if not in accordance with the position of either Buyer or Seller, shall not be in excess of the higher, nor less than the lower, of the amounts advocated by Seller in the Closing Date Prorated Prepaid Expense Statement or Buyer in the Prorated Prepaid Expense Statement Objection Notice with respect to such disputed item. Except as Seller and Buyer may otherwise agree, all communications between Seller and Buyer or any of their respective Representatives, on the one hand, and the Accountants, on the other hand, shall be in writing with copies simultaneously delivered to the non-communicating Party. The determination of the Accountants regarding the Closing Date Prorated Prepaid Expense Statement (and the Actual Prorated Prepaid Expense amount contained therein) shall be (A) the exclusive method for the resolution of disputes regarding the Closing Date Prorated Prepaid Expense Statement (absent manifest error), (B) delivered as soon as practicable following engagement of the Accountants, but in no event more than 60 days thereafter, and (C) shall be final, conclusive and binding upon Seller and Buyer (absent manifest error). Following delivery of the determination of the Accountants, the Parties shall revise the Closing Date Prorated Prepaid Expense Statement accordingly. The final value as of the Closing Date of the Prorated Prepaid Expenses, as determined pursuant to this Section 2.3.2(c), is the “**Final Closing Date Prorated Prepaid Expenses**”. Subject to the exercise by a Party of applicable rights of appeal under applicable Law, the Parties agree that judgment may be entered on such determination in any court having jurisdiction. The cost of the Accountants shall be borne by Buyer and Seller, in inverse proportion as they may prevail on the matters resolved by the Accountants, which proportionate allocation shall be calculated on an aggregate basis based on the relative dollar values of the amounts in dispute and shall be determined by the Accountants at the time the determination of such firm is rendered on the merits of the matters submitted.

(d) Within five Business Days after the date on which the Closing Date Prorated Prepaid Expense Statement (and the Actual Prorated Prepaid Expenses contained therein) becomes final and binding on Seller and Buyer in accordance with Section 2.3.2(c), (i) in the event that the Final Closing Date Prorated Prepaid Expenses is less than the Estimated Prorated Prepaid Expenses, the Purchase Price shall be adjusted downward by the amount by which the Estimated Prorated Prepaid Expenses exceeds the Final Closing Date Prorated Prepaid Expenses, and Seller shall pay the amount of such excess to Buyer and (ii) in the event that the Final Closing Date Prorated Prepaid Expenses is greater than the Estimated Prorated Prepaid Expenses, the Purchase Price shall be adjusted upward by the amount by which the Final Closing Date Prorated Prepaid Expenses exceeds the Estimated Prorated Prepaid Expenses, and Buyer shall pay the amount of such excess to Seller. All payments made pursuant to this Section 2.3.2(d) shall be made by wire transfer of immediately available funds to an account designated by the recipient in writing. Any payments made pursuant to this Section 2.3.2 shall be treated as an adjustment to the Purchase Price, including for Tax purposes, except as otherwise required by any Law.

2.4 Closing.

2.4.1 Closing. Pursuant to the terms and subject to the conditions of this Agreement, the closing of the Transactions (the “**Closing**”) shall take place at the Washington, DC offices of Covington & Burling LLP at 10:00 a.m., eastern time, on a Business Day on a date not later than two Business Days following satisfaction of all conditions (other than those that by their terms are to be satisfied or taken at the Closing) set forth in Article 6 (or, to the extent permitted by applicable Law, waived by the Party entitled to the benefits thereof), or such other time and place (including remotely by electronic exchange of executed signature pages) as Buyer and Seller may agree to in writing. The Closing shall be deemed to have occurred at 11:59:59 p.m., Eastern Time, on the Closing Date.

2.4.2 Closing Deliveries.

(a) At the Closing, Seller shall deliver the following to Buyer:

(i) each of the Ancillary Agreements (other than the Pharmacovigilance Agreement) to which Seller or any of its Affiliates is a party, executed by a duly authorized representative of Seller or its applicable Affiliate;

(ii) a certificate, executed by an officer of Seller and dated the Closing Date, confirming on behalf of Seller that the conditions set forth in Sections 6.2.1 and 6.2.2 have been satisfied;

(iii) [***]; and

(iv) except to the extent retained by Seller and delivered to Buyer in accordance with another provision of this Agreement or the Transition Services Agreement, the Purchased Assets; *provided*, that (A) with respect to tangible Purchased Assets, including the Purchased Inventory, delivery shall, unless the Parties otherwise mutually agree, be in accordance with Schedule 2.4.2(a)(iv), (B) with respect to the Purchased Regulatory Documentation and Purchased Product Records, Seller may, in its sole discretion, deliver electronic versions or physical copies, and (C) Seller may retain copies of the Purchased Regulatory Documentation and the Purchased Product Records (and, for the avoidance of doubt, prior to delivering or making available any files, documents, instruments, papers, books and records containing Purchased Product Records or constituting Purchased Regulatory Documentation, to Buyer, Seller shall be entitled to redact from such files, documents, instruments, papers, books and records any information to the extent that it does not relate to the Product Business) so long as, in the event Seller only provides electronic copies of any document for which Seller has a hard copy original version, Seller commits to provide Buyer, as promptly as reasonably practicable after Buyer's request therefor, access to such original documents in the event that such original version is needed to comply with any legal or regulatory requirement. If timely requested by Buyer, Seller will use commercially reasonable efforts to provide such requested original versions in such time frames as may be required by the regulatory agency or the appropriate legal forum. Any such copies of the Purchased Regulatory Documentation and the Purchased Product Records retained by Seller shall be considered Confidential Information of Buyer and subject to Section 5.4.

(b) At the Closing, Buyer shall deliver the following to Seller:

(i) the Closing Date Payment, in accordance with Section 2.3.1, reduced by any applicable withholding Taxes;

(ii) each of the Ancillary Agreements (other than the Pharmacovigilance Agreement) to which Buyer or any of its Affiliates is a party, executed by a duly authorized representative of Buyer or its applicable Affiliate; and

(iii) a certificate, executed by an officer of Buyer and dated the Closing Date, confirming on behalf of Buyer that the conditions set forth in Sections 6.3.1 and 6.3.2 have been satisfied.

2.5 Additional Consideration.

2.5.1 Milestone Payment.

(a) Subject to this Section 2.5, Buyer shall pay to Seller the following milestone payment (the "**Milestone Payment**") upon the achievement of the corresponding Milestone Event:

<u>Milestone Event</u>	<u>Milestone Payment</u>
Issuance of a FYCOMPA Patent Term Extension Certificate extending the term of U.S. Patent No. [***] to June 8, 2026	\$ 25,000,000

2.5.2 Buyer shall provide Seller with written notice within five Business Days of the achievement of the Milestone Event, including in such notice a copy of the Patent Term Extension Certificate extending the term of U.S. Patent No. [***] to June 8, 2026. Following receipt of such written notice, Seller shall issue an invoice to Buyer for the Milestone Payment and Buyer shall pay the Milestone Payment to Seller within 30 days of receipt of such invoice.

2.5.3 Royalty Payments.

(a) Subject to this Section 2.5, commencing on Loss of Exclusivity, for each Calendar Year during the Royalty Term, Buyer shall pay to Seller an amount based on a percentage of aggregate Net Sales of the Products in the Territory during such Calendar Year, which amount shall be calculated by multiplying the applicable percentage rate set forth below by the amount of incremental annual Net Sales of Products (the “**Royalty Payments**”):

<u>Net Sales</u>	<u>Rate prior to the date of Generic Entry</u>	<u>Rate on or after the date of Generic Entry</u>
If aggregate Net Sales are greater than [***] and less than [***].	[***]	[***]
If aggregate Net Sales are greater than [***] and less than [***].	[***]	[***]
If aggregate Net Sales are greater than [***].	[***]	[***]

Notwithstanding the foregoing, the Net Sales dollar amounts in the preceding table will be prorated for the Calendar Year in which Loss of Exclusivity occurs by multiplying each such amount by a fraction, the numerator of which is the number of days in such Calendar Year after Loss of Exclusivity occurs and the denominator of which is 365. For the avoidance of doubt, no amounts shall be due in respect of Net Sales following the Royalty Term.

(b) Buyer shall pay to Seller the Royalty Payments due with respect to a given Calendar Year within 15 days after the receipt of an invoice from Seller for such Royalty Payments, such invoice to be issued by Seller to Buyer following receipt of the Net Sales Report for such Calendar Year.

2.5.4 Net Sales Reporting.

(a) Buyer shall (i) 30 days following the beginning of each Calendar Year, commencing with the Calendar Year in which Loss of Exclusivity occurs, provide to Seller Buyer's good faith estimate of Net Sales of the Products for such Calendar Year, (ii) within five Business Days after the end of each Calendar Year, commencing with the Calendar Year in which Loss of Exclusivity occurs, provide to Seller Buyer's good faith estimate of Net Sales of the Products for such prior Calendar Year taking into account all deductions permitted by the definition of "Net Sales", and (iii) within 45 days after the end of each Calendar Year, commencing with the Calendar Year in which Loss of Exclusivity occurs, deliver to Seller a report (each, a "**Net Sales Report**") in a form reasonably acceptable to Seller setting out, on an aggregate basis and for each Product, (1) Net Sales during such prior Calendar Year, (2) taking into account all deductions permitted by the definition of "Net Sales", an itemized calculation of Net Sales, (3) a calculation of the amount of Royalty Payments, if any, due and payable on such Net Sales for such prior Calendar Year, and (4) a reconciliation of the amounts set forth in the Net Sales Report previously delivered for the prior Calendar Year to the amounts set forth in such Net Sales Report.

(b) In the event that, in connection with the reconciliation described in clause (4) of Section 2.5.4(a), Buyer determines that it made any Royalty Payment to Seller in respect of any prior Calendar Year in excess of the correct amount of the Royalty Payment applicable thereto, Buyer shall promptly advise Seller of its determination and, unless Seller objects to such determination in accordance with Section 2.5.4(e), shall be entitled to deduct the amount of such overpayment from the Royalty Payments due to Seller for the following Calendar Year (and, if applicable, successive Calendar Year until the amount of the overpayment has been reduced to zero.

(c) In the event that, in connection with the reconciliation described in clause (4) of Section 2.5.4(a), Buyer determines that an additional Royalty Payment for any prior Calendar Year is due to Seller, Buyer shall promptly advise Seller of its determination and, subject to Section 2.5.4(e), pay over such amounts to Seller within 30 days after the end of the Calendar Year in which such underpayment was discovered, plus interest on such amount in accordance with Section 2.5.6.

(d) Buyer shall, shall cause its Affiliates that are Contingent Payment Obligors, and shall use commercially reasonable efforts to cause the other Contingent Payment Obligors that are engaged in the sale of any Product to, keep reasonable, correct and complete books and records pertaining to the sales of the Products (including with respect to Net Sales thereof) to the extent required to calculate and verify all Royalty Payments payable hereunder ("**Net Sales Information**") and shall maintain the Net Sales Information until five years after the last day of the Calendar Year to which such Net Sales Information pertains. Upon Seller's request and subject to reasonable advance notice, Buyer shall, shall cause its Affiliates that are Contingent Payment Obligors, and shall use commercially reasonable efforts to cause each of the other Contingent Payment Obligors engaged in the sale of any Product to, permit an independent accounting firm of nationally recognized standing designated by Seller (the "**Auditor**") to inspect its books and records relating to the Net Sales Reports during normal business hours in order to confirm the accuracy and completeness of the Net Sales Information and Net Sales Reports and the amount of the Royalty Payments made hereunder. Such audits may not (i) be conducted more than once during or in respect of any Calendar Year; *provided*, that if any previous audit revealed an underpayment with respect to such period, Seller may conduct a second audit during such Calendar Year, or (ii) be conducted for any Calendar Year more than three years after the end of the Calendar Year to which such books and records pertain. The cost of any audit shall be borne by Seller, unless the audit reveals a variance of more than five percent from the Royalty Payments disclosed in any Net Sales Report, in which case Buyer shall bear the cost of the audit. Unless disputed pursuant to Section 2.5.4(e), if such audit concludes that (i) additional amounts were owed by Buyer to Seller, Buyer shall pay the additional amounts, with interest from the date originally due as provided in Section 2.5.6 or (ii) excess payments were made by Buyer to Seller, Seller shall reimburse such excess payments, in either case ((i) or (ii)), within 45 days after the date on which such audit is completed.

(e) In the event of a dispute with respect to any audit under Section 2.5.4(d), the Parties shall work in good faith to resolve the disagreement. If the Parties are unable to resolve any such dispute within 30 days, the disputing Party shall send written notice (the “**Audit Objection Notice**”) to the other Party, setting forth in specific detail the basis for its objection and its proposal for any adjustments to the amount of Royalty Payments subject to such audit, and the dispute shall be submitted for resolution to the Accountants. The Accountants shall be engaged at that time to review the Net Sales Information and Net Sales Reports and the amount of the Royalty Payments made thereunder, and shall make a determination as to the resolution of any adjustments. The Accountants shall be instructed, pursuant to an engagement letter, to resolve only those matters set forth in the Audit Objection Notice and not to otherwise investigate any matter independently and to act as an expert and not arbitrator. Buyer and Seller each agree to furnish to the Accountants such individuals and such information, books and records as may be reasonably required by the Accountants to make its final determination. Except as Seller and Buyer may otherwise agree, all communications between Seller and Buyer or any of their respective Representatives, on the one hand, and the Accountants, on the other hand, shall be in writing with copies simultaneously delivered to the non-communicating Party. The decision of the Accountants shall be final, conclusive and binding upon Seller and Buyer (absent manifest error). Subject to the exercise by a Party of applicable rights of appeal under applicable Law, the Parties agree that judgment may be entered on such determination in any court having jurisdiction. The costs of such Accountants as well as the initial audit shall be borne by Seller, unless the Accountants find or confirm a variance of more than five percent from the Royalty Payments that are the subject of such audit, in which case Buyer shall bear the cost of the audit. Not later than 30 days after such decision and in accordance with such decision, Buyer shall pay the additional amounts due to Seller, with interest from the date originally due as provided in Section 2.5.6 or Seller shall reimburse the excess payments to Buyer, as applicable.

(f) All information disclosed pursuant to Section 2.5.4(d) and Section 2.5.4(e) shall be subject to the confidentiality and non-use provisions set forth in Section 5.4 and the Parties shall cause the Auditors and Accountants, if any, to enter into a reasonably acceptable confidentiality agreement obligating such Person to retain all financial information in confidence pursuant to such confidentiality agreement.

2.5.5 Mode of Payment. The Milestone Payment and all Royalty Payments shall be made in U.S. dollars by wire transfer of immediately available funds in the requisite amount to the account(s) designated by Seller by notice to Buyer.

2.5.6 Interest on Late Payments. If Buyer shall fail to make a Milestone Payment or Royalty Payment when due, any such late payment shall bear interest at a per annum rate equal to the lesser of (a) the U.S. Prime Rate, as reported in *The Wall Street Journal* (eastern edition) for the first date on which such payment was delinquent, plus [***]% and (b) the maximum amount permitted by applicable Law, beginning on the first date on which payment was delinquent and ending on the date on which such payment is made, calculated based on the actual number of days such payment is overdue.

2.5.7 Commercially Reasonable Efforts. Commencing with the Calendar Year in which Loss of Exclusivity occurs and continuing until the expiry of the Royalty Term, Buyer shall, shall cause its Affiliates that are Contingent Payment Obligors to, and shall use commercially reasonable efforts to cause the other Contingent Payment Obligors to, use its and their, as applicable, Commercially Reasonable Efforts to Exploit the Products.

2.5.8 Transfer of Products. If Buyer transfers, sells, licenses, conveys or otherwise disposes a Product or any material rights or assets of Buyer or its Affiliates with respect to any Product, including its rights under U.S. Patent [***], to any Third Party, Buyer shall remain primarily responsible for all of its obligations under Section 2.5 for the duration of the Royalty Term.

2.5.9 Additional Consideration not Securities. The Parties acknowledge and agree that (a) the Milestone Payment and Royalty Payments are an integral part of the consideration payable to Seller in connection with the Transactions, (b) the right to receive any such payment shall not be represented by any form of certificate or other instrument and does not in any way constitute an equity ownership interest in the Party responsible for such payment, and (c) Seller has no rights as a security holder of Buyer as a result of Seller's right to receive the Milestone Payment and Royalty Payments.

2.5.10 Insolvency. Notwithstanding anything to the contrary in this Agreement, upon the occurrence of an Insolvency Event with respect to Buyer or an Affiliate of Buyer that controls Buyer, 100% of a due but unpaid Milestone Payment or any then-unpaid Royalty Payments related to any Net Sales that have occurred at or prior to such Insolvency Event shall be accelerated and become immediately due and payable. Nothing in this Agreement shall be construed, explicitly or implicitly, as consent or agreement by or on behalf of Seller to any proposed action by Buyer in a bankruptcy or insolvency proceeding, including any proposed assumption, assumption and assignment or other disposition of this Agreement.

2.5.11 PTE Certificate. [***].

2.6 Withholding. Buyer shall be entitled to deduct and withhold all Taxes that Buyer is required by applicable Law to deduct and withhold. Buyer shall timely pay such deducted and withheld amounts to the appropriate Governmental Authority. To the extent that such amounts are withheld and paid to the appropriate Governmental Authority, all such withheld amounts shall be treated as delivered to Seller hereunder. Buyer will promptly pay such withholding to the proper Governmental Authority and will furnish Seller with copies of any tax certificates or other documentation evidencing such withholding after remittance. Notwithstanding the foregoing, if Seller is entitled under any applicable Law to a reduction of rate of, or elimination of, applicable withholding amounts, it may deliver to Buyer or the appropriate Governmental Authority (with the reasonable cooperation of Buyer) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve Buyer of its obligation to withhold such amount and Buyer shall apply the reduced rate of withholding or dispense with withholding, as the case may be.

ARTICLE 3
REPRESENTATIONS AND WARRANTIES

3.1 Representations and Warranties of Seller. Seller represents and warrants to Buyer as follows, with each such representation and warranty subject to such exceptions, if any, as are set forth in the disclosure schedules delivered by Seller to Buyer concurrently with the execution and delivery of this Agreement and dated as of the date of this Agreement (the “**Disclosure Schedules**”). Disclosures in any section or paragraph or cross-referenced in the particular section of the Disclosure Schedules address the corresponding section or paragraph of this Agreement and other sections or paragraphs of this Agreement to the extent that it is reasonably apparent from its face that such disclosure is applicable to such other sections or paragraphs.

3.1.1 Corporate Status. Seller is a corporation duly organized, validly existing and in good standing under the Laws of Japan and has all requisite corporate power and authority to carry on the Product Business as now being conducted.

3.1.2 Authority.

(a) Seller has the requisite corporate power and authority to enter into and deliver this Agreement and the Ancillary Agreements to which it is a party, to perform its obligations hereunder and thereunder and to consummate the Transactions. The execution and delivery of this Agreement and the Ancillary Agreements to which Seller is or will be a party and the consummation by Seller of the Transactions have been duly authorized by all necessary corporate actions of Seller. This Agreement and each Ancillary Agreement to which Seller is or will be a party (assuming the due authorization, execution and delivery thereof by each other party thereto) constitutes or, upon the execution and delivery thereof by Seller, will constitute the valid and legally binding obligation of Seller, enforceable against Seller in accordance with their respective terms, subject to bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium or similar Laws of general application affecting or relating to the enforcement of creditors rights generally, and subject to equitable principles of general applicability, whether considered in a proceeding at law or in equity (collectively, the “**Enforceability Exceptions**”).

(b) Each Affiliate of Seller that is entering into an Ancillary Agreement has the requisite entity power and authority to perform its obligations under each Ancillary Agreement to which it will be a party and to consummate the Transactions. The execution and delivery of the Ancillary Agreements to which any Affiliate of Seller will be a party and the consummation of the Transactions have been or will be prior to the Closing duly authorized by all necessary organizational actions of such Affiliate. Each Ancillary Agreement (assuming the due authorization, execution and delivery thereof by each other party thereto) will, upon the execution and delivery thereof by the Affiliate of Seller that will be a party thereto, constitute the valid and legally binding obligation of such Affiliate of Seller, enforceable against such Affiliate in accordance with its terms, subject to the Enforceability Exceptions.

3.1.3 Non-Contravention. The execution, delivery and performance by Seller of this Agreement and each Ancillary Agreement to which it is a party and the execution, delivery and performance by each Affiliate of Seller of each Ancillary Agreement to which such Affiliate will be a party do not (a) violate the certificate of incorporation or bylaws or comparable organizational documents of Seller or such Affiliate, as applicable, (b) subject to compliance with any applicable Antitrust Law, violate any Law applicable to Seller or such Affiliate, as applicable, the Product Business or the Purchased Assets, or (c) subject to obtaining the consents, approvals and authorizations, making the filings and giving the notices referred to in Section 3.1.3 of the Disclosure Schedules or in Section 3.1.5(c), (i) violate, breach or constitute a default under, or result in the termination of, or give rise to a right of termination, cancellation or acceleration of any right or obligation under, any Transferred Contract, (ii) violate any order or judgment of a Governmental Authority in the Territory to which Seller or such Affiliate is subject to the extent relating to the Product Business or (iii) result in the imposition or creation of any Encumbrance other than a Permitted Encumbrance on any Purchased Asset, except, in the case of (b) and (c), for such violations, breaches, defaults, accelerations, cancellations, terminations or Encumbrances that would not reasonably be expected to have a Material Adverse Effect.

3.1.4 No Broker. There is no broker, finder, investment banker or financial advisor acting or who has acted on behalf of or based upon arrangements made by Seller or any of its Affiliates, who is entitled to receive any brokerage or finder's or other fee or commission from Buyer or any of its Affiliates in connection with the Transactions.

3.1.5 No Litigation; Consents.

(a) Neither Seller nor any of its Affiliates is engaged in any Litigation nor, to Seller's Knowledge, is there any Litigation threatened in writing against Seller or any of its Affiliates in the Territory with respect to a Product, the Product Business, the Purchased Assets or Assumed Liabilities.

(b) There is no order or judgment of a Governmental Authority in the Territory to which Seller or any of its Affiliates is subject with respect to a Product, the Product Business, the Purchased Assets or the Assumed Liabilities.

(c) Except for (i) if required, compliance with and filings or notifications required under any applicable Antitrust Law and the expiration or termination of the waiting periods thereunder, (ii) Authorizations that if not received, or declarations, filings or registrations that if not made, would not reasonably be expected to have a Material Adverse Effect, (iii) Authorizations, declarations, filings or registrations that have become applicable solely as a result of the specific regulatory status of Buyer or its Affiliates and (iv) items disclosed in Section 3.1.5(c) of the Disclosure Schedules, no notice to, filing with or Authorization of any Governmental Authority in the Territory is required for Seller to consummate the Transactions.

3.1.6 Title to and Sufficiency of the Purchased Assets.

(a) Seller and its Affiliates collectively own and have good and valid title to, or valid contract rights in, as applicable, the Purchased Assets (other than the Purchased Intellectual Property), free and clear of all Encumbrances other than Permitted Encumbrances.

(b) The Purchased Assets, together with (i) the Product supplied, Intellectual Property Rights licensed, services provided and rights granted to Buyer and its Affiliates under this Agreement and the Ancillary Agreements, (ii) the real property and general corporate and support services and functions provided by Seller and its Affiliates to the Product Business prior to the Closing, (iii) the assets, rights and properties described in clauses (a) through (o) of the definition of "Excluded Assets" and (iv) the types of assets listed on Section 3.1.6(b) of the Disclosure Schedules, constitute all of the material rights, property and assets necessary to conduct the Product Business as conducted by Seller and its Affiliates.

3.1.7 Contracts. Each of the Transferred Contracts is in effect and constitutes a legal, valid and binding agreement of Seller or an Affiliate of Seller, enforceable against Seller or its applicable Affiliate and, to Seller's Knowledge, each other party thereto, in accordance with its terms, subject to the Enforceability Exceptions. Neither Seller, its applicable Affiliates nor, to Seller's Knowledge, any other party thereto is in material breach or material default in the performance, observance or fulfillment of any obligation or covenant contained in any Transferred Contract. Neither Seller nor its applicable Affiliates has received any written notice from a Third Party (a) stating that such Third Party intends to terminate, or modify or amend in any material respect, any Transferred Contract or (b) alleging that Seller or its applicable Affiliate is in breach or default in the performance, observance or fulfillment of any material obligation or covenant contained in any Transferred Contract, in each case ((a) and (b)), other than any such notices that have been withdrawn or relate to a breach or default that has been cured. Neither Seller nor its applicable Affiliate has given any written notice to any Third Party stating that Seller or such Affiliate intends to terminate, or modify or amend in any material respect, any Transferred Contract. A true and complete (except with respect to any redaction of terms that are unrelated to the Product) copy of each Transferred Contract, including all schedules, exhibits, appendices, amendments, modifications and waivers relating thereto, has been made available to Buyer.

3.1.8 Compliance with Law. Seller and its Affiliates, and to Seller's Knowledge, the Third Parties that have been engaged by Seller and its Affiliates in the conduct of the Product Business, are, and in the last three years have been, in compliance with all applicable Laws in the Territory with respect to the conduct of the Product Business and the ownership of and use of the Purchased Assets, including (i) any applicable Laws in the Territory governing the development, approval, Manufacture, sale, marketing, promotion or distribution of drugs and the purchase or prescription of or reimbursement for drugs by any Governmental Authority, private health plan or entity, or individual, and (ii) the U.S. Foreign Corrupt Practices Act (15 U.S.C. §§78dd-1 et seq.), the U.S. Anti-Kickback Statute (42 U.S.C. §1320a-7(b)), the U.S. False Claims Act (31 U.S.C. §§ 3729, et seq.), and the U.S. Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. §1320d et. seq.), except for noncompliance that would not reasonably be expected to materially and adversely impact the Product Business. In the three years prior to the date hereof, neither Seller nor any of its Affiliates has received any written notice alleging that Seller or any of its Affiliates were in material violation of any Law in the Territory applicable to the conduct of the Product Business or the ownership and use of the Purchased Assets or the Non-Exclusive IPR.

3.1.9 Regulatory Matters.

(a) Seller, or an Affiliate of Seller, is the sole and exclusive owner of each Purchased Regulatory Approval. The Purchased Regulatory Approvals (i) have been validly granted or acknowledged by the relevant Governmental Authority; and (ii) are in full force and effect. During the three years prior to the date hereof, neither Seller nor any of its Affiliates has received any written communication from any Governmental Authority in the Territory threatening to revoke, withdraw, modify, suspend, cancel or terminate any Purchased Regulatory Approval. No Litigation is pending or, to Seller's Knowledge, threatened regarding the suspension or revocation of any Purchased Regulatory Approval. Neither Seller nor any of its Affiliates is in material violation of the terms of any Purchased Regulatory Approval. Neither Seller nor any of its Affiliates has granted any right of reference to any Purchased Regulatory Approval to any Third Party for use in the Territory other than in the ordinary course of business.

(b) During the three years prior to the date hereof, with respect to the Products in the Territory, neither Seller nor any of its Affiliates nor, to Seller's Knowledge, any Third Party contract manufacturer engaged by Seller or any of its Affiliates to Manufacture a Product has received any Form 483s, warning letters or other similar written correspondence from any applicable Regulatory Authority with respect to a Product in which such Regulatory Authority asserted that the operations of Seller or its Affiliates or such Third Party contract manufacturer were not in material compliance with applicable Law.

(c) During the three years prior to the date hereof, (i) there has not been any product recall, dear doctor letter, post-sale warning, safety notice, investigator notice or other notice of action relating to the safety or efficacy of any Product or its compliance with relevant regulations, or market withdrawal or replacement conducted by or on behalf of Seller or any of its Affiliates in the Territory concerning a Product and to Seller's Knowledge, no events exist that might reasonably require Seller or its relevant Affiliate to conduct the same, and (ii) neither Seller nor any of its Affiliates has received any written notice that any Governmental Authority in the Territory has commenced, or threatened to initiate, any action to request a recall of a Product in the Territory. Seller has made available to Buyer copies of all written notices of alleged defect or Adverse Events regarding the Product in the Territory received by Seller or its Affiliates from any Governmental Authority in the Territory in the three years prior to the date hereof.

(d) During the three years prior to the date hereof, all units of Product distributed and sold in the Territory have been Manufactured in compliance in all material respects with applicable Law, including cGMP, and the applicable Regulatory Approvals and Product specifications. Neither Seller nor any of its Affiliates has received written notice of any Product Liability Claim with respect to the Product in the Territory in the past three years prior to the date hereof.

(e) All material reports, registrations, filings or submissions with respect to a Product that were required to be filed in the last three years with the FDA or any other similar Regulatory Authority in the Territory have been filed. All such reports and filings were in compliance in all material respects with applicable Laws when filed or as amended or supplemented, and no material deficiencies have been asserted in writing to Seller or any of its Affiliates by any such Regulatory Authority with respect to such reports and filings that have not been cured. Seller and its Affiliates are and for the last three years have been in compliance in all material respects with, or possess and have possessed for the last three years, all licenses, permits and approvals necessary for the conduct of the Product Business.

(f) None of Seller, its Affiliates or any of their respective employees or, to Seller's Knowledge, any consultant of Seller who has undertaken activities for or on behalf of the Product Business in the three years prior to the date hereof, has been debarred or deemed subject to debarment pursuant to Section 306 of the Act, nor, to Seller's Knowledge, are any such Persons the subject of a conviction described in such section.

(g) Except as set forth in Section 3.1.9(g) of the Disclosure Schedules, during the three years prior to the date hereof, no clinical trials, including, to Seller's Knowledge, investigator initiated studies, for which Seller or any of its Affiliates have supplied Product, of the Product have been conducted or expressly permitted to be conducted by or on behalf of Seller or any Affiliate of Seller in the Territory.

3.1.10 Taxes.

(a) All required Tax Returns relating to Taxes concerning or attributable to Seller's operation of the Product Business or the Purchased Assets have been prepared and timely filed. Such Tax Returns are true and correct in all material respects and have been completed in accordance with applicable Law. Seller has paid all Taxes it has been required to pay and that are due and payable with respect to the Product Business or Purchased Assets. Seller has timely withheld with respect to its employees and other Third Parties, in each case, to the extent engaged in the Product Business (and has timely paid over, or will timely pay over, any withheld amounts to the appropriate Taxing Authority) any income, wage and other Taxes it has been required to withhold under applicable Law.

(b) There are no Encumbrances for Taxes on the Purchased Assets other than Permitted Encumbrances.

(c) Seller does not know of any basis for the assertion of any claim for any Liabilities for unpaid Taxes for which Buyer would become liable as a result of the transactions contemplated by this Agreement or any Ancillary Agreement, or that would result in any Encumbrance (other than a Permitted Encumbrance) on any of the Purchased Assets. To the extent applicable to the Purchased Assets or Buyer's ownership of the Purchased Assets, (i) no audit or other examination of any Tax Return of Seller is presently in progress, nor has Seller been notified of any request for such an audit or other examination; (ii) no adjustment relating to any Tax Return filed by Seller has been proposed in writing by any Taxing Authority to Seller or any representative thereof; and (iii) no claim has ever been made by a Taxing Authority in a jurisdiction where Seller does not file Tax Returns that it is or may be subject to taxation by that jurisdiction.

3.1.11 Intellectual Property.

(a) Seller or an Affiliate of Seller owns, and has the right to transfer to Buyer, the Purchased Intellectual Property, free and clear of all Encumbrances, except for any Permitted Encumbrances, subject to the terms of the Contracts set forth in Section 3.1.11(d) of the Disclosure Schedules. Seller or an Affiliate of Seller owns or Controls the Non-Exclusive IPR and has the right to grant to Buyer the license set out at Section 2.1.2(a).

(b) Section 3.1.11(b) of the Disclosure Schedules sets forth a true and complete list of all Purchased Intellectual Property owned by Seller or its Affiliates that has issued, been registered or granted or that is the subject of an application for registration, issuance or grant in the Territory and that has not expired or lapsed or been abandoned or withdrawn (“**Registered IP**”). All maintenance fees, annuity fees or renewal fees for such Registered IP in the Territory that are due and payable prior to the Closing have been paid. Section 3.1.11(b) of the Disclosure Schedules sets forth each filing, payment and action that must be taken on or before the date that is 120 days after Closing in order to maintain the Registered IP in the Territory.

(c) All Registered IP is subsisting and, to Seller’s Knowledge, all Registered IP that has been registered, granted or issued, is valid and enforceable. None of the Purchased Patents are subject to any Litigation, challenge, reissue, reexamination, opposition or interference and, to Seller’s Knowledge, no Litigation, challenge, reissue, reexamination, opposition or interference has been threatened against Seller or its Affiliates in writing with respect to the Purchased Patents. None of the Purchased Copyrights, Purchased Domain Names or Purchased Trademarks are subject to any currently pending Litigation, cancellation, concurrent use or opposition and, to Seller’s Knowledge, no Litigation, cancellation, concurrent use or opposition has been threatened against Seller or its Affiliates in writing with respect to the Purchased Copyrights, Purchased Domain Names or Purchased Trademarks.

(d) Except with respect to any licenses to any off-the-shelf software or any other intellectual property that is licensed or otherwise made available pursuant to a click-wrap, shrink-wrap or similar agreement or on a subscription basis, and other non-exclusive licenses or rights granted to or by Third Parties in the ordinary course of business, Section 3.1.11(d) of the Disclosure Schedules sets forth a true and complete list of all written licenses, sublicenses and similar Contracts (i) pursuant to which Seller or any of its Affiliates obtained the right to use or practice under any Intellectual Property Right of a Third Party that is used exclusively in the conduct of the Product Business as conducted as of the date hereof, or (ii) pursuant to which Seller or any of its Affiliates has granted a Third Party the right to use or practice under (A) any of the Purchased Intellectual Property or (B) any Intellectual Property Right of a Third Party that is used exclusively in the conduct of the Product Business as conducted as of the date hereof.

(e) No Litigation is pending or, to Seller’s Knowledge, threatened in writing against Seller or any of its Affiliates as of the date hereof (i) alleging that the conduct of the Product Business as conducted as of the date hereof infringes or misappropriates the Intellectual Property Rights of any Third Party in the Territory or (ii) challenging, or seeking to deny or restrict, the use of any of the Purchased Intellectual Property or any of Seller’s or its Affiliates’ rights therein. To Seller’s Knowledge, neither the Exploitation nor the Manufacturing of the Products in or for the Territory or the conduct of the Product Business as conducted as of the date hereof infringes or misappropriates the Intellectual Property Rights of any Third Party in the Territory.

(f) To Seller’s Knowledge, no Third Party is engaging in any activity in the Territory that infringes, misappropriates or makes unauthorized use of (A) any of the Purchased Intellectual Property or (B), to the extent such infringement, misappropriation or unauthorized use could have a materially adverse effect on the Product Business, any of the Non-Exclusive IPR.

(g) Except as set forth in Section 3.1.11(g) of the Disclosure Schedules, as of the date hereof, Seller has not received a Paragraph IV Notice from any applicant for a Generic Product.

(h) Seller and its applicable Affiliates have taken reasonable measures to maintain in confidence: (i) all trade secrets and other material confidential information included in the Purchased Know-How and (ii) all material trade secrets and, to Seller's Knowledge, other material confidential information included in the Non-Exclusive IPR. To Seller's Knowledge, none of such (i) trade secrets or other material confidential information included in the Purchased Know-How or (ii) material trade secrets or other material confidential information included in the Non-Exclusive IPR have been disclosed to any Person by Seller or its Affiliates except pursuant to commercially reasonable non-disclosure or license agreements. No current or former employee, consultant or independent contractor of Seller or any of its Affiliates has any claim of ownership in or to any Purchased Intellectual Property owned by Seller or its Affiliates. Each Person who has any rights in or to any of the Purchased Patents has executed an agreement with Seller assigning all of such rights, and the inventions described or claimed therein, to the owner of such Purchased Patent.

(i) (A) Except as set forth in Section 3.1.11(i)(A) of the Disclosure Schedules, Seller has not received written notice from any Person, including without limitation the U.S. Patent and Trademark Office, challenging in writing the validity or enforceability of any Purchased Patents. To Seller's Knowledge, there is no *ex parte* or *inter partes* proceeding involving a third party pending at the United States Patent and Trademark Office with regard to any Purchased Patents and (B) except as set forth in Section 3.1.11(i)(B) of the Disclosure Schedules, the Purchased Patents are not subject to any outstanding order of, judgment of, decree of, determination of, or agreement with, any Governmental Authority adversely affecting the use thereof by Seller or its rights thereto.

(j) To Seller's Knowledge, no funding, facilities or resources of any Governmental Authority or any university, college, other educational institution or research center were used in the creation or development of the Purchased Patents and no Governmental Authority or any university, college, other educational institution or research center has any claim or right in or to any Purchased Patents or any clinical or nonclinical data related to any Product or the Purchased Patents. To Seller's Knowledge, no current or former employee, consultant or independent contractor, who was involved in, or who contributed to, the creation or development of any Purchased Patents, has performed services for a Governmental Authority, a university, college, or other educational institution, or a research center, during a period of time during which such employee, consultant or independent contractor was also performing services used in the creation or development of the Purchased Patents.

3.1.12 Product Financial Information. Section 3.1.12 of the Disclosure Schedules sets forth the annual gross sales and net sales (and certain components thereof) for the Products in the Territory for Seller's fiscal years ended March 31, 2021 and 2022 (the "**Financial Information**"). The Financial Information has been prepared in accordance with GAAP from the books and records of Seller or its applicable Affiliate and fairly presents in all material respects the annual gross sales and net sales (and certain components thereof) for the Products for the periods indicated.

3.1.13 Purchased Inventory.

(a) The Purchased Inventory is owned by Seller or its Affiliates free and clear of all Encumbrances (other than Permitted Encumbrances). All of the Purchased Inventory was Manufactured packaged, handled, stored and transported in accordance with and complies in all material respects with cGMP and all applicable Laws and complies with the applicable Purchased Regulatory Approvals and Product specifications, and is usable and saleable, in the ordinary course of the Product Business.

3.1.14 Conduct of the Business.

(a) In the twelve months prior to the Closing Date, there has been no change in stock levels outside the ordinary course of the Product Business caused by unreasonable changes in the business practices of Seller or its Affiliate(s) in relation to sales, discounting and delivery of Product(s) to customers not consistent with previous practices.

(b) During the twelve months prior to the date of this Agreement, no customer of Seller or its Affiliates with respect to the Product Business has: (i) stopped, or indicated an intention to stop, purchasing the Product(s) in the Territory, or (ii) reduced, or indicated an intention to reduce, substantially, its purchasing of the Product(s) in the Territory.

3.2 Representations and Warranties of Buyer. Buyer represents and warrants to Seller as follows:

3.2.1 Corporate Status. Buyer is a corporation duly organized, validly existing and in good standing under the Laws of the State of Delaware. Each Affiliate of Buyer that is entering into an Ancillary Agreement is a legal entity duly organized, validly existing and in good standing under the Laws of its organization.

3.2.2 Authority.

(a) Buyer has the requisite corporate power and authority to enter into this Agreement and the Ancillary Agreements to which it is or will be a party, to perform its obligations hereunder and thereunder and to consummate the Transactions. The execution and delivery of this Agreement and the Ancillary Agreements to which Buyer is or will be a party and the consummation by Buyer of the Transactions have been duly authorized by the necessary corporate actions of Buyer. This Agreement and each Ancillary Agreement to which Buyer is or will be a party (assuming the due authorization, execution and delivery hereof by each other party thereto) constitute or, upon the execution and delivery thereof by Buyer, will constitute the valid and legally binding obligations of Buyer, enforceable against Buyer in accordance with their respective terms, subject to the Enforceability Exceptions.

(b) Each Affiliate of Buyer that is entering into an Ancillary Agreement has the requisite entity power and authority to perform its obligations under each Ancillary Agreement to which it will be a party and to consummate the Transactions. The execution and delivery of the Ancillary Agreements to which any Affiliate of Buyer will be a party and the consummation of the Transactions have been or will be prior to the Closing duly authorized by all necessary organizational actions of such Affiliate. Each Ancillary Agreement (assuming the due authorization, execution and delivery thereof by each other party thereto) will, upon the execution and delivery thereof by the Affiliate of Buyer that will be a party thereto, constitute the valid and legally binding obligation of such Affiliate of Buyer, enforceable against such Affiliate in accordance with its terms, subject to the Enforceability Exceptions.

3.2.3 Non-Contravention. The execution, delivery and performance by Buyer of this Agreement and of each Ancillary Agreement to which it is a party and the execution, delivery and performance by each Affiliate of Buyer of each Ancillary Agreement to which such Affiliate will be a party do not (a) violate the organizational documents of Buyer or such Affiliate of Buyer, (b) subject to compliance with any applicable Antitrust Law, violate any Law or other restriction of any Governmental Authority applicable to Buyer or such Affiliate of Buyer or (c) subject to obtaining the Authorizations, making the filings and giving the notices referred to in Section 3.2.5(b), (i) violate, breach or constitute a default under or result in the termination of, or give rise to a right of termination, cancellation or acceleration of any right or obligation under, any Contract to which Buyer or such Affiliate of Buyer is a party or (ii) violate any order or judgment of a Governmental Authority to which Buyer or such Affiliate of Buyer is subject, except with respect to clauses (b) and (c), for violations, breaches, defaults, terminations, cancellations or accelerations that would not reasonably be expected to have a Buyer Material Adverse Effect.

3.2.4 No Broker. There is no broker, finder, financial advisor or other Person acting or who has acted on behalf of Buyer or its Affiliates, who is entitled to receive any brokerage or finder's or financial advisory fee from Seller or any of its Affiliates in connection with the Transactions.

3.2.5 Litigation; Consents.

(a) Except as would not reasonably be expected to have a Buyer Material Adverse Effect, as of the date hereof, (i) there is no Litigation pending or, to Buyer's knowledge, threatened against Buyer or any of its Affiliates by or before any Governmental Authority, or (ii) order or judgment of a Governmental Authority to which Buyer or any of its Affiliates is subject.

(b) Except for (i) if required, compliance with and filings or notifications required under any applicable Antitrust Law and the expiration or termination of the waiting periods thereunder, and (ii) Authorizations that if not received, or declarations, filings or registrations that if not made, would not reasonably be expected to have a Buyer Material Adverse Effect, no notice to, filing with or Authorization of, any Governmental Authority or other Person is required for Buyer to consummate the Transactions.

3.2.6 Solvency. After giving effect to the Transactions, including the payment of the Purchase Price and all other amounts required to be paid by Buyer and its Affiliates in connection with the consummation of the Transactions, Buyer will not (a) be insolvent (because (i) Buyer's financial condition is such that the sum of its debt is greater than the fair value of its assets, (ii) the present fair saleable value of Buyer's assets will be less than the amount required to pay Buyer's probable liability on its debts as they become absolute and matured or (iii) Buyer is unable to pay all of its debt as and when they become due and payable), (b) have unreasonably small capital with which to engage in its business or (c) have incurred or plan to incur debts beyond its ability to pay as they become absolute and matured.

3.2.7 Financial Capacity. Buyer has, and on the Closing Date will have, immediately available cash that is sufficient to enable it to pay the full consideration payable hereunder and to make all other payments required to be made by Buyer in connection with the Transactions and to pay all fees and expenses of Buyer and its Affiliates incurred in connection with the Transactions.

3.2.8 Debarred Personnel. None of Buyer, any of Buyer's Affiliates or any of their respective employees or, to Buyer's knowledge, any consultant of Buyer, has been debarred or deemed subject to debarment pursuant to Section 306 of the Act in the three years prior to the date hereof, nor to Buyer's knowledge, are any such Persons the subject of a conviction described in such section.

3.3 Exclusivity of Representations; Acknowledgements of Buyer .

3.3.1 BUYER ACKNOWLEDGES AND AGREES THAT, EXCEPT FOR THE EXPRESS REPRESENTATIONS AND WARRANTIES CONTAINED IN SECTION 3.1 OR MADE BY SELLER OR ITS AFFILIATES IN THE ANCILLARY AGREEMENTS, (A) NEITHER SELLER NOR ANY OF SELLER'S AFFILIATES HAS MADE ANY REPRESENTATION OR WARRANTY WHATSOEVER HEREIN OR OTHERWISE RELATED TO THE TRANSACTIONS, INCLUDING WITH RESPECT TO ANY INFORMATION, DOCUMENTS, OR MATERIALS FURNISHED TO OR FOR BUYER BY SELLER OR ANY OF ITS AFFILIATES OR ANY OF THEIR RESPECTIVE REPRESENTATIVES, INCLUDING ANY INFORMATION, DOCUMENTS, OR MATERIALS MADE AVAILABLE TO BUYER IN ANY "DATA ROOM," MANAGEMENT PRESENTATION, OR ANY OTHER FORM IN CONNECTION WITH THE TRANSACTIONS AND (B) BUYER HAS NOT RELIED ON ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED IN CONNECTION WITH THE TRANSACTIONS.

3.3.2 SELLER ACKNOWLEDGES AND AGREES THAT, EXCEPT FOR THE EXPRESS REPRESENTATIONS AND WARRANTIES CONTAINED IN SECTION 3.2 OR MADE BY BUYER IN THE ANCILLARY AGREEMENTS, (A) BUYER HAS MADE NO REPRESENTATION OR WARRANTY WHATSOEVER HEREIN OR OTHERWISE RELATED TO THE TRANSACTIONS AND (B) SELLER HAS NOT RELIED ON ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED IN CONNECTION WITH THE TRANSACTIONS.

3.3.3 BUYER ACKNOWLEDGES AND AGREES THAT THE REPRESENTATIONS AND WARRANTIES OF SELLER IN SECTION 3.1.11(E) SECTION 3.1.11(F) AND SECTION 3.1.11(G) CONSTITUTE THE SOLE REPRESENTATIONS AND WARRANTIES OF SELLER WITH RESPECT TO INFRINGEMENT AND MISAPPROPRIATION OF INTELLECTUAL PROPERTY.

ARTICLE 4
PRE-CLOSING COVENANTS

4.1 Access and Information.

4.1.1 During the period commencing on the date hereof and ending on the earlier to occur of (a) the Closing and (b) the termination of this Agreement in accordance with Article 8 (the “**Pre-Closing Period**”), Seller shall afford Buyer and its Representatives continued reasonable access to the Representatives and, through an electronic data room, to the books and records, of Seller and its Affiliates, to the extent related to the Products, the Product Business, the Purchased Assets and the Assumed Liabilities, and during such period, shall provide to Buyer such information, books and records to the extent that they relate to the Products, the Product Business, the Purchased Assets and the Assumed Liabilities, as Buyer may reasonably request (*provided*, that Seller shall only be required to use its commercially reasonable efforts to provide Buyer any such information, books and records that are in the possession or control of a Third Party), in each case for the purpose of enabling Buyer to verify the accuracy of Seller’s representations and warranties contained in this Agreement and as may be agreed by Buyer and Seller as useful and allowable for post-Closing integration planning; *provided, however*, that such access shall not unreasonably disrupt Seller’s ordinary course operations. Notwithstanding anything to the contrary contained in this Agreement, Seller shall not be required to disclose any information or provide any such access if such disclosure or access would reasonably be expected, in Seller’s reasonable judgment, to (i) violate (A) applicable Law, including applicable Antitrust Laws, or (B) any binding agreement entered into by Seller prior to the date hereof, or prior to the Closing Date to the extent entered into in the ordinary course of business, including any confidentiality agreement to which Seller is a party (*provided*, that Seller shall use commercially reasonable efforts to obtain consent from any Third Party to any such binding agreement to enable Seller to disclose such information), (ii) jeopardize any attorney/client privilege or other established legal privilege, or (iii) disclose any trade secrets not included in the Purchased Assets; *provided*, that Seller shall provide Buyer with a general description of the type of any such information withheld by Seller to the extent that Seller is permitted to do so.

4.1.2 During the Pre-Closing Period, Buyer hereby agrees that, except as agreed upon by Seller, neither it nor any of its Affiliates or Representatives shall contact any licensor, competitor, supplier, distributor or customer of, or service provider to, Seller with respect to the Products, the Purchased Assets, the Product Business, this Agreement, the Ancillary Agreements or the Transactions.

4.1.3 Within ten (10) Business Days prior to the Closing Date, Seller shall deliver to Seller an up-to-date, complete, and accurate list of all rights of reference to any Purchased Regulatory Approval that have been granted by Seller or its Affiliates to any Third Party other than in the ordinary course of business.

4.2 Supplement to Disclosure Schedules. [*].**

4.3 Ordinary Course of Business.

4.3.1 During the Pre-Closing Period, except (a) as set forth in Schedule 4.3.1 of the Disclosure Schedules or as otherwise required by this Agreement or any Ancillary Agreement, (b) as required by applicable Law, (c) COVID-19 Response Actions, (d) as required by the terms of any agreement binding upon Seller or its Affiliates that has been made available to Buyer, (e) for any actions taken by Seller that are reasonably necessary or useful to consummate the Transactions or (f) as Buyer shall otherwise consent in writing, which consent shall not be unreasonably withheld, conditioned or delayed, (x) Seller shall use commercially reasonable efforts to conduct the Product Business in substantially the same manner as heretofore conducted and in the ordinary course of business and shall use its commercially reasonable efforts to preserve substantially intact the Product Business, and substantially preserve the current relationships of the Product Business with customers, suppliers and other Persons with which the Product Business has material business relations and (y) neither Seller nor its Affiliates shall (it being understood and agreed that Seller and its Affiliates compliance with this clause (y) shall in no event result in a breach of the preceding clause (x)):

(i) transfer, sell, lease, license or create any Encumbrance (other than any Permitted Encumbrance) on any of the material Purchased Assets, or abandon, fail to maintain or allow to lapse any material Purchased Intellectual Property, in each case, other than in the ordinary course of business;

(ii) terminate any Transferred Contract, or make any material amendment to or waive any material right or remedy under any Transferred Contract, or, except as otherwise permitted under this Section 4.3.1, enter into any Contract with respect to the Product Business under which aggregate payments made or received by Seller or its Affiliates exceed \$[***] or that in any way materially impairs or restricts the conduct of the Product Business;

(iii) discharge, settle, compromise, satisfy or consent to any entry of any judgment with respect to, any Litigation that (A) results in any material restriction on the Product Business or any Product or (B) results in a Liability to the extent that such Liability would constitute an Assumed Liability;

(iv) vary any inventory practices with respect to any Product in the Territory in any respect materially inconsistent with past practice other than in response to *bona fide* customer orders;

(v) adopt a plan of complete or partial liquidation or dissolution, recapitalization or other reorganization affecting the Purchased Assets, the Product Business, or any Product; or

(vi) agree, in writing or otherwise, to take any of the foregoing actions.

4.3.2 Nothing contained in this Agreement is intended to give Buyer or its Affiliates, directly or indirectly, the right to control, direct or influence the Product Business prior to the Closing, and nothing contained in this Agreement is intended to give Seller or its Affiliates, directly or indirectly, the right to control, direct or influence Buyer's operations. Prior to the Closing, each of Buyer, on the one hand, and Seller and its Affiliates, on the other hand, shall exercise, consistent with the terms and conditions of this Agreement, complete control and supervision over its and its Affiliates respective operations.

4.4 Obligation to Consummate the Transaction. Each of the Parties agrees that, subject to this Section 4.4 and Section 4.5, it shall use its reasonable best efforts to take, or cause to be taken, all action, and to do, or cause to be done, all things necessary, proper or advisable to the extent permissible under applicable Law, to consummate and make effective the Transactions and to ensure that the conditions set forth in Article 6 are satisfied, insofar as such matters are within the control of either of them. Without limiting the generality of the foregoing, during the Pre-Closing Period, as soon as reasonably practicable after the date hereof, Seller shall use its reasonable best efforts (not requiring the payment of money, the commencement of any Litigation or offer or grant any accommodation (financial or otherwise) to any Third Party) to obtain the consents, permits and authorizations, make the filings and issue the notices (in each case, if any) disclosed in Section 3.1.3 or Section 3.1.5(c) of the Disclosure Schedules. Prior to the Closing, Buyer shall cooperate with Seller, upon the request of Seller, in connection with Seller obtaining any such consent, permit or authorization, making such filings and issuing such notices; *provided*, that, except as provided in Section 4.5, such cooperation shall not include any requirement of Buyer or any of its Affiliates to pay money to any Third Party, commence any Litigation or offer or grant any accommodation (financial or otherwise) to any Third Party in connection with such efforts. In addition to the foregoing, Buyer agrees, subject to any applicable obligations of confidentiality, to provide such evidence as to its financial capability, resources and creditworthiness as may be reasonably requested by any Third Party whose consent is sought hereunder.

4.5 Efforts; Regulatory and Other Authorizations; Notices and Consents.

4.5.1 Buyer and the Seller shall, and shall cause its Affiliates to, (a) use reasonable best efforts to promptly obtain all consents, approvals or authorizations of, or make registrations, declarations or filings with all Governmental Authorities and officials that may be or become necessary or advisable for its execution and delivery of, and the performance of its obligations pursuant to, this Agreement (including receiving or obtaining the termination or expiration of any waiting periods applicable under any Antitrust Law, Foreign Merger Control Law, or similar Law), (b) cooperate with the other in promptly seeking to obtain all such consents, approvals or authorizations, or registrations, declarations, filings, or expiration or termination of any such waiting period, and (c) provide such other information to any Governmental Authority as such Governmental Authority may request in connection herewith. The Parties agree to, and, if applicable, shall cause their Affiliates to, file promptly (but in no event later than 10 Business Days after the date hereof) any Notification and Report Forms and related material required to be filed with the United States Federal Trade Commission and the Antitrust Division of the United States Department of Justice under the HSR Act with respect to the Transactions, and to supply as promptly as practicable to the appropriate Governmental Authorities any additional information and documentary material that may be requested pursuant to the HSR Act. The Parties agree to, and, if applicable, shall cause their Affiliates to, make as promptly as practicable any filings and notifications, jointly determined by the Parties to be required for consummation of the Transactions, under any applicable foreign antitrust, competition, or trade regulation Law (“**Foreign Merger Control Laws**”) and to supply as promptly as practicable to the appropriate Governmental Authorities any additional information and documentary material that may be requested pursuant to such Foreign Merger Control Law. Neither Buyer, on the one hand, nor Seller, on the other hand, may (or may permit any of their respective Affiliates to), without the consent of the other Party, (i) cause any such filing or submission applicable to it to be withdrawn or refiled for any reason, including to provide the applicable Governmental Authority with additional time to review the Transactions, or (ii) consent to any voluntary extension of any statutory deadline or waiting period or to any voluntary delay of the consummation of the Transactions at the behest of any Governmental Authority. Buyer shall pay all fees (including the HSR Act filing fee) to any Governmental Authority in order to obtain any such consents, approvals or authorizations of, or registrations, declarations or filings.

4.5.2 Without limiting the generality of Buyer’s undertaking pursuant to Section 4.5.1, Buyer agrees to, and to cause its Affiliates to, take any and all steps necessary or advisable to (a) avoid or eliminate any impediment under any Antitrust Law that may be asserted by any Governmental Authority or any other Person, so as to enable the Parties to close the Transactions as promptly as practicable, and in any event prior to the End Date, and (b) prevent a prohibition decision or the entry of any order or judgment (or if such order or judgment is so entered, to eliminate such order or judgment or otherwise cause it to be satisfied or cease to be a restraint on the Transactions) sought by any Governmental Authority or private Person under any Antitrust Law that would result in the failure of any condition to the obligations of the Parties to consummate the Transactions to be satisfied. Such steps may include proposing, negotiating, committing to and effecting, whether effected by consent decree, hold separate order or otherwise, (i) the sale, divestiture, license or disposition of such of its or its Affiliates respective assets, properties or businesses, (ii) terminating any of its or its Affiliates existing relationships and contractual rights and obligations, (iii) entering into such other arrangements, as are necessary or advisable in order to avoid the entry of, and the commencement of litigation seeking the entry of, or to effect the dissolution of, any injunction, temporary restraining order or other order in any suit or proceeding, which would otherwise have the effect of materially delaying or preventing the consummation of the Transactions, or (iv) committing to take any action which Buyer is capable of taking, including agreements that limit Buyer’s freedom of action with respect to the Products, the Product Business, the Purchased Assets and the Assumed Liabilities. In addition, Buyer shall, and shall cause its Affiliates to, defend through litigation on the merits any claim arising under any Antitrust Laws asserted by any Person in order to avoid entry of, or to have vacated or terminated, any order or judgment (whether temporary, preliminary or permanent) that would prevent the Closing prior to the End Date. For the avoidance of doubt, Buyer’s obligations under this Section 4.5.1 shall be absolute and not qualified by “commercially reasonable efforts,” “reasonable best efforts” or “best efforts.”

4.5.3 To the extent permitted by applicable Law or the applicable Antitrust Authority, each of Buyer, on the one hand, and Seller, on the other hand, shall promptly notify the other of any communication it or any of its Affiliates receives from any Antitrust Authority relating to the matters that are the subject of this Agreement and permit the other to review and comment upon in advance any proposed communication by such Party to any Antitrust Authority. Unless required by an Antitrust Authority, neither Buyer, on the one hand, nor Seller, on the other hand, shall (or permit any of their respective Affiliates to) agree to participate in any communication with such Antitrust Authority in respect of any filings, investigation (including any settlement of the investigation), litigation or other inquiry unless it consults with the other in advance and, to the extent permitted by such Antitrust Authority, gives the other the opportunity to attend and participate at such communication. Buyer, on the one hand, and Seller, on the other hand, will, and will cause their respective Affiliates to, coordinate and cooperate fully with each other in exchanging such information and providing such assistance as the other may reasonably request in connection with the foregoing and in seeking early termination of any applicable waiting periods, including under the HSR Act. Buyer, on the one hand, and Seller, on the other hand, will promptly provide each other with copies of all substantive correspondence, filings or communications between them or any of their Representatives or Affiliates, on the one hand, and any Antitrust Authority or members of its staff, on the other hand, with respect to this Agreement and the Transactions; *provided, however*, that such materials may be redacted (x) to remove references concerning the valuation of the Products, the Product Business or Purchased Assets, (y) as necessary to comply with contractual arrangements, and (z) as necessary to address reasonable attorney-client privilege or confidentiality concerns, to the extent that such attorney-client privilege or confidentiality concerns are not governed by a common interest privilege or doctrine.

4.5.4 Buyer shall not, and shall cause its Affiliates not to, enter into any transaction (including any merger or acquisition), or any Contract to effect any transaction, that might reasonably be expected to make it more difficult, or to increase the time required, to: (a) obtain the expiration or termination of the waiting period under the HSR Act, or approval under any Foreign Merger Control Law, applicable to the Transactions; (b) avoid the entry of, or the commencement of litigation seeking the entry of, or to effect the dissolution of, any injunction, temporary restraining order or other order that would materially delay or prevent the consummation of the Transactions; or (c) obtain all consents, approvals or authorizations of, or registrations, declarations or filings of Governmental Authorities necessary for the consummation of the Transactions.

4.6 Notices. During the Pre-Closing Period, each Party shall promptly, after any of its officers obtains actual knowledge of such matter, notify the other Party of the occurrence of any event or condition or the existence of any fact that may reasonably be expected to cause any of the conditions to the obligations of the other Party to consummate the Transactions set forth in Article 6 not to be satisfied, or any written notice or other written communication received by such from a Governmental Authority or from any Person indicating that the Transactions may require such Person's consent; *provided, however*, that an unintentional failure to give notice under this Section 4.6 shall not be deemed to be a breach of covenant under this Section 4.6 and shall constitute only a breach of any underlying representation, warranty, covenant or agreement, as the case may be, that resulted in the need to provide such notice.

ARTICLE 5
ADDITIONAL COVENANTS

5.1 Cooperation in Litigation and Investigations. Subject to Section 5.4, Section 7.2.2 and Section 7.2.3, and except as set forth in any Ancillary Agreement, Buyer and Seller shall reasonably cooperate with each other in the defense or prosecution of any Litigation, examination or audit instituted prior to the Closing or which may be instituted thereafter against or by either Party relating to or arising out of the conduct of the Product Business prior to or after the Closing (other than Litigation or claims between Buyer and Seller or their respective Affiliates arising out of the Transactions). In connection therewith, and except as set forth in any Ancillary Agreement, each of Seller and Buyer shall make available to the other during normal business hours and upon reasonable prior written notice, but without unreasonably disrupting its business, all records relating exclusively to the Purchased Assets, the Assumed Liabilities and the Excluded Liabilities held by it and reasonably necessary to permit the defense or investigation of any such Litigation, examination or audit (other than Litigation or claims between Buyer and Seller or their respective Affiliates arising out of the Transactions), and shall preserve and retain all such records for the length of time contemplated by its standard record retention policies and schedules; *provided*, that Seller shall not be required to make available such documents if such disclosure could, in Seller's reasonable discretion, (a) violate applicable Law or any binding agreement entered into prior to the Closing Date (including any confidentiality agreement to which Seller or any of its Affiliates is a party), *provided*, that Seller uses commercially reasonable efforts to obtain waivers of any such binding agreement, (b) jeopardize any attorney-client privilege or other established legal privilege or (c) disclose any trade secrets. The Party requesting such cooperation shall pay the reasonable out-of-pocket costs and expenses of providing such cooperation (including legal fees and disbursements) incurred by the Party providing such cooperation and by its officers, directors, employees and agents.

5.2 Further Assurances.

5.2.1 Each of Seller and Buyer shall, at any time or from time to time, at the request and expense of the other, execute and deliver to the other all such instruments and documents or further assurances as the other may reasonably request in order to (a) vest in Buyer all of the rights, title and interests of Seller and its Affiliates in and to the Purchased Assets, as contemplated hereby, (b) effectuate Buyer's assumption of the Assumed Liabilities and (c) grant to each Party all rights contemplated herein to be granted to such Party under the Ancillary Agreements; *provided, however*, that apart from such foregoing customary further assurances, neither Seller nor Buyer shall have any other obligations except as specifically set forth and described herein or in the Ancillary Agreements. Without limitation of the foregoing, except as expressly set forth herein or in the Ancillary Agreements, (i) Seller shall not have any obligation to assist or otherwise participate in the amendment or supplementation of any Regulatory Approval or otherwise to participate in any filings or other activities relating to any Regulatory Approval other than as necessary to effect the transfer of Seller's or its Affiliates' rights with respect thereto to Buyer in connection with the Closing pursuant to this Agreement, and (ii) Buyer shall be responsible for filing with the U.S. Patent and Trademark Office the Trademark Assignment Agreement and for transferring registered ownership of the Purchased Domain Names and all costs and expenses in connection with the foregoing.

5.2.2 To the extent that Seller's rights under any Purchased Asset may not be assigned without the approval, consent or waiver of another Person and such approval, consent, authorization or waiver has not been obtained prior to the Closing, this Agreement shall not constitute an agreement to assign the same if an attempted assignment would constitute a breach thereof or be unlawful. If any such approval, consent, authorization or waiver shall not have been obtained prior to the Closing, Seller shall, for a period of up to 12 months after the Closing (or, if shorter, the remaining term of any relevant Purchased Asset for which any such approval, consent or waiver is required) (a) use its commercially reasonable efforts to assist and cooperate with Buyer in order for Buyer to obtain all necessary approvals, consents, authorizations and waivers to the assignment and transfer thereof; *provided*, that neither Seller nor any of its Affiliates shall be required to pay money to any Third Party, commence any Litigation or offer or grant any accommodation (financial or otherwise) to any Third Party in connection with such efforts and (b) prior to any such approval, consent, authorization or waiver being obtained and the related Purchased Asset being transferred and assigned to Buyer or Buyer's designee, use its commercially reasonable efforts to enter into such arrangements to provide to Buyer substantially comparable benefits thereof and enforce, at the request of and for the account of Buyer, any rights of Seller arising under any such Purchased Asset against any Person. To the extent that Buyer is provided with benefits of any such Purchased Asset, Buyer shall perform or fully enable Seller to perform the obligations of Seller thereunder.

5.2.3 Buyer agrees that, except in respect of any Transferred Contract to the extent set forth in the Transition Services Agreement, Seller and its Affiliates shall not have any liability whatsoever to Buyer arising out of or relating to the failure to obtain any approval, consent, authorization or waiver that may be required in connection with this Agreement or because of the termination of any Contract as a result thereof. Buyer further agrees that no representation, warranty or covenant of Seller contained herein shall be breached or deemed breached, and no condition shall be deemed not satisfied, as a result of (a) the failure to obtain any such approval, consent, authorization or waiver, (b) any such termination or (c) any action commenced or threatened in writing by or on behalf of any Person arising out of or relating to the failure to obtain any such approval, consent, authorization or waiver or any such termination.

5.3 Publicity.

5.3.1 No public announcement related to this Agreement or the Transactions will be issued without the joint approval of Seller and Buyer, which approval shall not be unreasonably withheld, conditioned or delayed, except in any public disclosure which either Seller or Buyer, in its good faith judgment, believes is required by applicable Law or by any stock exchange on which its securities or those of its Affiliates are listed. If either Party, in its good faith judgment, believes such disclosure is required, such Party will use its commercially reasonable efforts to consult with the other Party and its Representatives, and to consider in good faith any revisions proposed by the other Party or its Representatives, as applicable, prior to making (or prior to any of its Affiliates making) such disclosure, and shall limit such disclosure to only that information which is legally required to be disclosed. Notwithstanding the foregoing, without the approval of the other Party, subject to the other terms and conditions of this Agreement (including Section 5.4), (a) Buyer and Seller and their respective Affiliates may communicate with Governmental Authorities and Seller and its Affiliates may communicate with their customers, suppliers, distributors or other Persons engaged in the Product Business, regarding this Agreement, the Ancillary Agreements and the Transactions, including in order to obtain consents of or from any such Person necessary or desirable to effect the consummation of the Transactions, and (b) Buyer and Seller and their respective Affiliates may make public announcements and engage in public communications regarding this Agreement, the Ancillary Agreements and the Transactions, in the case of this clause (b), to the extent such announcements or communications are consistent with the Parties' prior public communications made in compliance with this Section 5.3.

5.3.2 If Buyer or any of its Affiliates, based on the advice of its counsel, determines that this Agreement, or any of the other Ancillary Agreements, must be publicly filed with a Governmental Authority, then Buyer or its applicable Affiliate, prior to making any such filing, shall provide Seller and its counsel with a redacted version of this Agreement (and any other Ancillary Agreement) that it intends to file and consider in good faith any comments provided by Seller or its counsel thereto, and use commercially reasonable efforts to ensure the confidential treatment by such Governmental Authority of those sections specified by Seller or its counsel for redaction and confidentiality.

5.3.3 Notwithstanding any other provision of this Agreement, the requirements of this Section 5.3 shall not apply to any disclosure of Seller, Buyer, or any of their respective Affiliates, of any information concerning this Agreement or the Transactions in connection with any dispute between the Parties or their respective Affiliates regarding this Agreement, the Ancillary Agreements, or the Transactions.

5.4 Confidentiality.

5.4.1 All Confidential Information provided by one Party (or its Representatives or Affiliates) (collectively, the “**Disclosing Party**” with respect to such information) to the other Party (or its Representatives or Affiliates) (collectively, the “**Receiving Party**” with respect to such information) shall be subject to and treated in accordance with the terms of this Section 5.4. As used in this Section 5.4, “**Confidential Information**” means, as to a Party (a) all information disclosed by such Party (or its Representatives or Affiliates) to the Receiving Party in connection with this Agreement, any Ancillary Agreement or the Transactions, including all information with respect to the Disclosing Party’s licensors, licensees or Affiliates, (b) all information disclosed to the Receiving Party by the Disclosing Party under the Confidentiality Agreement and (c) all memoranda, notes, analyses, compilations, studies and other materials prepared by or for the Receiving Party to the extent containing or reflecting the information in the preceding clause (a) or (b). The terms of this Agreement and the Ancillary Agreements shall be deemed both Buyer Confidential Information and Seller Confidential Information. Notwithstanding the foregoing, Confidential Information shall not include information that, in each case as demonstrated by competent written documentation:

(i) was already known to the Receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the Disclosing Party;

Party; (ii) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;

(iii) became generally available to the public or otherwise part of the public domain after its disclosure to the Receiving Party other than through any act or omission of the Receiving Party in breach of this Agreement or the Confidentiality Agreement;

(iv) is subsequently disclosed to the Receiving Party by a Third Party without obligations of confidentiality to the Disclosing Party with respect thereto; or

(v) is subsequently independently discovered or developed by the Receiving Party without the aid, application or use of Confidential Information of the Disclosing Party.

5.4.2 The Confidentiality Agreement shall expire and be of no further force and effect upon the Closing; *provided, however*, such expiration of the Confidentiality Agreement shall in no way prejudice or adversely affect the ability of either party thereto after the Closing to seek damages, or any other remedy available to such party, with respect to a violation by the other party (or such other party's Affiliates or Representatives) of the Confidentiality Agreement relating to Confidential Information (as defined therein) prior to the Closing.

5.4.3 From and after the Closing, all Confidential Information obtained by Seller (or its Affiliates or Representatives) from Buyer (or its Affiliates or Representatives) and all Confidential Information to the extent relating exclusively to the Product Business, the Purchased Assets and the Assumed Liabilities (collectively, the "**Buyer Confidential Information**") shall be deemed to be Confidential Information disclosed by Buyer to Seller for purposes of this Section 5.4, and, during the period from the Closing through the [***] anniversary of the Closing Date or, if longer, with respect to any such information that constitutes a trade secret under applicable Law, until such time as such information no longer constitutes a trade secret under applicable Law (the "**Confidentiality Period**"), shall be used by Seller, its Affiliates or their respective Representatives solely as required to (a) perform their respective obligations or exercise or enforce their respective rights and remedies under this Agreement (including Seller's and its Affiliates exercise of the rights retained or granted pursuant to Section 2.1.2, Section 5.7.2 or 5.7.3) or any Ancillary Agreement, (b) comply with applicable Law or its or its Affiliates' respective regulatory, stock exchange, Tax, accounting or financing reporting requirements, (c) to pursue insurance claims or other recoveries with respect to a Product or arising out of or related to the Transactions or (d) undertake activities in support of Buyer's operations in the Territory (each of (a) through (d), a "**Seller Permitted Purpose**"), and for no other purpose. During the Confidentiality Period, Seller shall not (i) disclose, or permit the disclosure of, any of the Buyer Confidential Information to any Person except those Persons to whom such disclosure is necessary in connection with any Seller Permitted Purpose and who are advised of the confidential nature of the Confidential Information and directed to comply with the confidentiality and non-use obligations under this Section 5.4 or (ii) use the Buyer Confidential Information except in connection with any Seller Permitted Purpose. Seller shall treat, and will cause its Affiliates and the Representatives of Seller or any of its Affiliates to treat, the Buyer Confidential Information as confidential, using the same degree of care as Seller normally employs to safeguard its own confidential information from unauthorized use or disclosure, but in no event less than a reasonable degree of care. Seller shall be responsible for any use or disclosure of Buyer Confidential Information by any of Seller's Affiliates or Representatives that would breach this Section 5.4 if such Affiliate or Representative was a party hereto.

5.4.4 During the Confidentiality Period, all Confidential Information obtained by Buyer (or its Affiliates or Representatives) from Seller (or its Affiliates or Representatives) other than the Buyer Confidential Information (the “**Seller Confidential Information**”) shall be used by Buyer solely as required to (a) perform its obligations or exercise or enforce its rights and remedies under this Agreement or any Ancillary Agreement, (b) comply with applicable Law or its or its Affiliates’ respective regulatory, stock exchange, Tax, accounting or financing reporting requirements, (c) to pursue insurance claims or other recoveries with respect to a Product or arising out of or related to the Transactions, or (d) solely with respect to Confidential Information in respect of the Non-Exclusive IPR, conduct the Product Business following the Closing (each of (a) through (d), a “**Buyer Permitted Purpose**”), and for no other purpose. During the Confidentiality Period, Buyer shall not (i) disclose, or permit the disclosure of, any of Seller Confidential Information to any Person except those Persons to whom such disclosure is necessary in connection with a Buyer Permitted Purpose and who are advised of the confidential nature of the Confidential Information and directed to comply with the confidentiality and non-use obligations under this Section 5.4, or (ii) use, or permit the use of, Seller Confidential Information, except in connection with a Buyer Permitted Purpose. Buyer shall treat, and will cause its Affiliates and the Representatives of Buyer or any of its Affiliates to treat, Seller Confidential Information as confidential, using the same degree of care as Buyer normally employs to safeguard its own confidential information from unauthorized use or disclosure, but in no event less than a reasonable degree of care. Buyer shall be responsible for any use or disclosure of Seller Confidential Information by any of Buyer’s Affiliates or Representatives that would breach this Section 5.4 if such Affiliate or Representative was a party hereto. For clarity, all Confidential Information with respect to the Non-Exclusive IPR shall be Seller Confidential Information.

5.4.5 In the event either Party is requested pursuant to, or required by, applicable Law, including stock exchange listing rules and regulations, to disclose any of the other Party’s Confidential Information (*i.e.*, Seller Confidential Information or Buyer Confidential Information, as applicable), it will notify the other Party in writing in a timely manner so that such Party may seek a protective order or other appropriate remedy or, in such Party’s sole discretion, waive compliance with the confidentiality provisions of this Agreement. Each Party will cooperate in all reasonable respects in connection with any reasonable actions to be taken for the foregoing purpose, at the sole cost and expense of the Party seeking such remedy or order. In any event, the Party requested or required to disclose such Confidential Information may furnish it as requested or required pursuant to applicable Law (subject to any such protective order or other appropriate remedy) without liability hereunder, *provided* that such Party furnishes only that portion of the Confidential Information which such Party is advised by an opinion of its counsel is legally required, and if confidential treatment is available such Party exercises reasonable efforts to obtain reliable assurances that confidential treatment will be accorded to such Confidential Information, at the sole cost and expense of the other Party.

5.4.6 Nothing in this Section 5.4 shall be construed as preventing or in any way inhibiting either Party from complying with applicable Law governing activities and obligations undertaken pursuant to this Agreement or any Ancillary Agreement in any manner which it reasonably deems appropriate.

5.5 Commercialization. Except to the extent otherwise provided in the Transition Services Agreement, as between Seller and its Affiliates and Buyer and its Affiliates, (a) Buyer, at its own cost and expense, shall be responsible for and have sole discretion over the commercialization, marketing strategy, promotion, distribution and sale of the Products in the Territory and shall independently determine and set prices for the Products in the Territory, including the selling price, volume discounts, Rebates and similar matters; [***]; (b) Buyer shall be responsible, at its own cost and expense, for all marketing, advertising and promotional materials related to the Products in the Territory; and (c) Buyer or its Affiliates shall be responsible for receiving and processing all orders, undertaking all invoicing, collection and receivables, and providing all customer service related to the sale of the Products in the Territory.

5.6 Regulatory Transfers.

5.6.1 [*].**

5.6.2 Each Party shall bear its own costs and expenses in connection with the transfer of the Purchased Regulatory Approvals to Buyer or its Affiliates; *provided, however*, that Buyer shall be responsible for the payment of any filing or similar fees payable to the applicable Governmental Authority with respect to the transfer of the Purchased Regulatory Approvals.

5.7 Regulatory Responsibilities.

5.7.1 [*].**

5.7.2 [*].**

5.7.3 [*].**

5.8 Pharmacovigilance. Pharmacovigilance responsibilities in the Territory with respect to the Products shall be transferred from Seller or its applicable Affiliates to Buyer or its applicable Affiliates in accordance with the Transition Services Agreement, including the provision of the post-marketing safety data maintained by Seller and its Affiliates with respect to the Products. Seller shall maintain the global safety database for the Product and shall be responsible for all pharmacovigilance activities for the Products outside the Territory, including preparation of safety reports, safety signaling and for sharing safety information with applicable Regulatory Approval Holders, and Buyer shall be responsible for such pharmacovigilance activities for the Products within the Territory, in each case, in accordance with the Pharmacovigilance Agreement, which shall be entered into by the Parties within 60 days following the Closing Date.

5.9 Medical and Other Inquiries; Recalls.

5.9.1 Except to the extent otherwise provided in the Transition Services Agreement, Buyer or its designee, from and after the Closing, (a) shall be responsible for, and shall handle and respond to, all customer complaints and inquiries (including medical and non-medical inquiries) related to a Product in the Territory, and (b) shall be responsible for, and shall conduct, all correspondence and communication with physicians and other health care professionals in the Territory relating to a Product. Buyer, or its respective designees, shall keep such records and make such reports as shall be reasonably necessary to document such communications in compliance with applicable Law.

5.9.2 From the Closing Date until the transfer of the NDAs comprised within the Purchased Regulatory Approvals to Buyer or its designee, Seller shall have control, in consultation with Buyer (to the extent that is possible pursuant to applicable Law), over whether to conduct a recall or market withdrawal, as applicable, of any unit of Product sold in the Territory and the manner in which any such recall or market withdrawal shall be conducted. In the event of a dispute or disagreement between the Parties with respect to any such recall or market withdrawal, such dispute shall be referred to the Chief Medical and Regulatory Officer of the Buyer and to the Chief Strategy Officer of Seller for resolution. If such executives cannot resolve such matter within three days after the date of the matter is referred to them (or such shorter period as may be required by the circumstances), then the decision of Seller shall be the final decision with respect to such matter. From the effective date of transfer of the NDAs comprised within the Purchased Regulatory Approvals to Buyer or its designee, Buyer or its relevant Affiliate or designee shall have control over whether to conduct a recall or market withdrawal, as applicable, of any unit of Product sold in the Territory and the manner in which any such recall or market withdrawal shall be conducted.

5.10 Wrong Pockets.

5.10.1 Assets. For a period of up to 18 months after the Closing Date, if either Buyer or Seller becomes aware that any of the Purchased Assets has not been transferred to Buyer or that any of the Excluded Assets has been transferred to Buyer, it shall promptly notify the other Party in writing and the Parties shall, as soon as reasonably practicable, ensure that such property is transferred, with any necessary prior Third Party consent or approval, to (a) Buyer, in the case of any Purchased Asset which was not transferred to Buyer at the Closing; or (b) Seller, in the case of any Excluded Asset which was transferred to Buyer.

5.10.2 Payments. If, on or after the Closing Date, either Party shall receive any payments or other funds due to the other Party pursuant to the terms of this Agreement or any Ancillary Agreement, then the Party receiving such funds shall, within 30 days after receipt of such funds, forward such funds to the proper Party, subject to Section 5.11.1. The Parties acknowledge and agree there is no right of offset regarding such payments and a Party may not withhold funds received from Third Parties for the account of the other Party in the event there is a dispute regarding any other issue under this Agreement or any of the Ancillary Agreements.

5.11 Accounts Receivable; Accounts Payable.

5.11.1 Accounts Receivable. The Parties acknowledge and agree that all Accounts Receivable shall remain the property of Seller or its applicable Affiliate and shall be collected by Seller or its Affiliates subsequent to the Closing. In the event that, subsequent to the Closing, Buyer or an Affiliate of Buyer receives any payments from any obligor with respect to an Account Receivable, then Buyer shall, within 30 days after receipt of such payment, remit the full amount of such payment to Seller. In the case of the receipt by Buyer of any payment from any obligor of both Seller and Buyer then, unless otherwise specified by such obligor, such payment shall be applied first to amounts owed to Buyer with the excess, if any, remitted to Seller. In the event that, subsequent to the Closing, Seller or any of its Affiliates receives any payments from any obligor with respect to an account receivable of Buyer for any period after the Closing Date, then Seller shall, within 30 days after receipt of such payment, remit the full amount of such payment to Buyer. In the case of the receipt by Seller of any payment from any obligor of both Seller and Buyer then, unless otherwise specified by such obligor, such payment shall be applied first to amounts owed to Seller with the excess, if any, remitted to Buyer.

5.11.2 Accounts Payable. In the event that, subsequent to the Closing, Buyer or an Affiliate of Buyer receives any invoices from any Third Party with respect to any account payable of the Product Business outstanding prior to the Closing, then Buyer shall, within 30 days after receipt of such invoice, provide such invoice to Seller. In the event that, subsequent to the Closing, Seller or any of its Affiliates receives any invoices from any Third Party with respect to any account payable of Buyer or any of its Affiliates with respect to the Product Business for any period after the Closing, then Seller shall, within 30 days after receipt of such invoice, provide such invoice to Buyer.

5.11.3 Financial Information. Within 55 days following the Closing Date and continuing until such time as Buyer files the Carve-Out Financial Statements with the Securities and Exchange Commission, Seller shall cause its auditors to provide to Buyer audited and unaudited financial statements for the Product Business as of the dates and for the periods as are jointly agreed to by Seller and Buyer and their respective auditors no later than 10 days after the date hereof (the “**Carve-Out Financial Statements**”), and, if applicable, Seller shall provide and shall use its commercially reasonable efforts to cause its Affiliates and Representatives to provide, information requested by Buyer and reasonably necessary to prepare any applicable pro forma financial information required to be filed by Buyer with the Securities and Exchange Commission in connection with the Transactions. The Carve-Out Financial Statements (a) will be derived from Seller’s historical financial statements, (b) will be prepared in accordance with GAAP throughout the periods covered thereby, (c) comply as to form in all material respects with clause (e) of Rule 3-05 of Regulation S-X, and (d) accurately present in all material respects the information required to be presented with respect to the Product Business under clause (e) of Rule 3-05 of Regulation S-X for the periods covered thereby. Buyer shall be solely responsible for any information it files with or furnishes to the Securities and Exchange Commission and shall promptly reimburse Seller for all out-of-pocket costs and expenses reasonably incurred by Seller and its Affiliates in connection with complying with this Section 5.11.3.

5.12 Certain Tax Matters.

5.12.1 Transfer Taxes and Apportioned Obligations.

(a) Each of Buyer and Seller shall each be responsible for fifty percent (50%) of any recordation, transfer, documentary, excise, sales, value added, use, stamp, foreign withholding, conveyance or other similar Taxes, duties or governmental charges, and all recording or filing fees or similar costs, imposed or levied by reason of, in connection with or attributable to this Agreement and the Ancillary Agreements or the Transactions (collectively, “**Transfer Taxes**”), and such Party shall pay all amounts due and owing in respect of any Transfer Taxes at the rate in force at the due time for payment or such other time as is stipulated under applicable Law.

(b) All personal property and similar ad valorem Taxes levied with respect to the Purchased Assets for a taxable period which includes (but does not end on) the Closing Date (collectively, the “**Apportioned Obligations**”) shall be apportioned between Seller and Buyer based on the number of days of such taxable period ending on the day prior to the Closing Date (such portion of such taxable period, the “**Pre-Closing Tax Period**”) and the number of days of such taxable period on and after the Closing Date (such portion of such taxable period, the “**Post-Closing Tax Period**”). Seller shall be liable for the proportionate amount of such Apportioned Obligations that is attributable to the Pre-Closing Tax Period, and Buyer shall be liable for the proportionate amount of such Apportioned Obligations that is attributable to the Post-Closing Tax Period.

(c) Apportioned Obligations and Transfer Taxes shall be timely paid, and all applicable filings, reports and returns shall be filed, as provided by applicable Law. The Party (or its Affiliate) that files a Tax Return with respect to any Apportioned Obligation or Transfer Tax shall, at its own expense, file such Tax Return with respect to the relevant Transfer Tax or Apportioned Obligation, and if required by applicable Law, the non-filing Party shall join in the execution of any such Tax Returns and other documentation. The Party that files (or whose Affiliate files) a Tax Return covering any Apportioned Obligations shall be responsible for paying such Apportioned Obligations to the applicable Taxing Authority. With respect to the Apportioned Obligations and Transfer Taxes, the paying Party shall be entitled to reimbursement from the non-paying Party in accordance with Sections 5.12.1(a) and 5.12.1(b). Upon payment of any such Apportioned Obligation or Transfer Tax, the paying Party shall present a statement to the non-paying Party setting forth the amount of reimbursement to which the paying Party is entitled under Sections 5.12.1(a) and 5.12.1(b) together with such supporting evidence as is reasonably necessary to calculate the amount to be reimbursed. The non-paying Party shall make such reimbursement promptly but in no event later than 10 days after the presentation of such statement.

5.12.2 Cooperation and Exchange of Information. Each of Seller and Buyer shall (a) provide the other with such assistance as may reasonably be requested by the other in connection with the preparation of any Tax Return, audit or other examination by any taxing authority or judicial or administrative proceeding relating to Liability for Taxes in connection with the Product Business or the Purchased Assets, (b) retain and provide the other with any records or other information that may be relevant to such Tax Return, audit or examination, proceeding or determination and (c) inform the other of any final determination of any such audit or examination, proceeding or determination that affects any amount required to be shown on any Tax Return of the other for any period.

5.12.3 Refunds. Buyer will pay to Seller any refunds of Taxes received by Buyer or any of its Affiliates with respect to the Product Business or the Purchased Assets that relate to a Pre-Closing Tax Period attributable to Taxes that were paid by Seller at any time or were reflected in the determination of the Purchase Price, net of (1) Taxes payable by the Buyer or any of its Affiliates in obtaining such refund and (2) any reasonable out-of-pocket costs. Seller shall reimburse Buyer for any reasonable out-of-pocket expenses incurred in connection with such good faith efforts. Buyer will make payment of any such refund to Seller with ten Business Days after the actual receipt of such refund of Taxes.

5.12.4 Survival of Tax Covenants. The covenants contained in this Section 5.12 shall survive until 30 days after the expiration of the applicable statute of limitations (including extensions thereof).

5.13 NDC Numbers; Returns; Payment Claims; Price Reporting.

5.13.1 NDC Numbers; Product Labeling.

(a) [***].

(b) [***].

5.13.2 Returns. From and after the Closing, Buyer and Seller will administer all returns of Product, and all payments and refunds therefor, in accordance with the Transition Services Agreement.

5.13.3 Payment Claims; Price Reporting. From and after the Closing, responsibility for Payment Claims and price reporting to Third Party customers, including applicable Governmental Authorities, shall be allocated between the Parties in accordance with the Transition Services Agreement.

5.13.4 Government Contracts. Buyer shall use Commercially Reasonable Efforts to enter into Contracts for the Products with applicable Governmental Authorities in the Territory as soon as is reasonably practicable following the Closing Date (but in no event later than March 31, 2023, except to the extent otherwise provided in the Transition Services Agreement), that are sufficient to permit the Products to be removed from the Government Contracts covering the Products.

5.14 Retained Names and Marks.

5.14.1 Retained Names and Marks.

(a) Buyer hereby acknowledges that Seller or its Affiliates own all right, title and interest in and to the company names, trade names, logos, trade dress and other Trademark rights set forth on Schedule 5.14.1 (collectively, the “**Retained Names and Marks**”), and that, except as expressly provided below, neither Buyer nor its Affiliates shall have any right to use the Retained Names and Marks.

(b) Subject to the terms and conditions of this Agreement, Buyer shall, during the Applicable Transition Period, be entitled to use (and shall have a limited non-exclusive, non-transferable license to use, with the right to sublicense to distributors and subcontractors in the ordinary course of business, the Retained Names and Marks solely as such Retained Names and Marks are used therein or thereon) all of the Product Business's existing stocks of promotional materials, including all website content and such other documents and materials in existence and included within the Purchased Product Records (collectively, the "**Existing Stock**"), in each case, containing the Retained Names and Marks solely in connection with the operation of the Product Business as operated immediately prior to Closing, after which Applicable Transition Period, Buyer shall cause the removal or obliteration of all Retained Names and Marks from such Existing Stock or cease using such Existing Stock; *provided* that Buyer may only use Existing Stock during the Applicable Transition Period to the extent it is impracticable for Buyer to use remove or obliterate the Retained Names and Marks from such Existing Stock prior to the use thereof, or to use, in lieu of Existing Stock, content, documents and materials that do not contain the Retained Names and Marks.

(c) Subject to the terms and conditions of this Agreement and the Transition Services Agreement, Seller (on behalf of itself and its Affiliates) hereby grants to Buyer and its Affiliates a limited, non-exclusive, royalty-free, non-assignable (except in accordance with Section 9.7) license to use, with the right to sublicense to distributors and subcontractors in the ordinary course of business, (i) the Retained Names and Marks solely in the Territory and solely to identify Seller or any of its Affiliates as the manufacturer of the Purchased Inventory and of any units of Product supplied under the Transition Services Agreement ("**Supplied Product**") on the Product Labeling for such Purchased Inventory and Supplied Product solely to the extent such identification is required by applicable Law and solely to the extent that Seller or any of its Affiliates is the manufacturer of such Purchased Inventory or Supplied Product, (ii) Seller's Product Labeling solely in the distribution and sale of any Purchased Inventory and Supplied Product in the Territory, which license in (i) and (ii) shall terminate on the earlier to occur of (x) the expiry of the Applicable Transition Period and (y) the termination of such license in accordance with this Section 5.14.1(c). Seller shall have the right to terminate the licenses to the Retained Names and Marks under this Section 5.14.1 upon written notice to Buyer, if Buyer is in material breach of its obligations under this Section 5.14 with respect to the Retained Names and Marks and has failed to cure such material breach within 30 days (or such other time period as the Parties may agree) following written notice from Seller of such material breach. Following the Applicable Transition Period or the earlier termination thereof as permitted in this Section 5.14.1(c), Buyer shall cease all use of the Retained Names and Marks on any Purchased Inventory or on any Supplied Product.

(d) During and after the Applicable Transition Period, Buyer shall not, and shall and hereby does cause its Affiliates not to, adopt, use, register or seek to register any Trademark, or any domain name or social media identifier that contains a term, that is substantially similar to, confusingly similar to or dilutive of any of the Retained Names and Marks (together with all variations, translations, transliterations and acronyms thereof).

5.14.2 Limitation of Rights; Quality Standards.

(a) Except as expressly provided in this Section 5.14, no right to use the Retained Names and Marks is granted by Seller or its Affiliates to Buyer or its Affiliates, whether by implication or otherwise, and nothing hereunder permits Buyer or its Affiliates to use the Retained Names and Marks in any manner, other than as expressly permitted under this Section 5.14, or to register or seek to register, or to permit any Third Party to register or to seek to register in any jurisdiction, any of the Retained Names and Marks. Neither Seller nor any of its Affiliates shall have any obligation hereunder to maintain or undertake, the registration, maintenance, prosecution or defense of any of the Retained Names and Marks.

(b) Buyer shall ensure that all use of the Retained Names and Marks as permitted in this Section 5.14 shall (i) comply with all trademark usage restrictions or other guidelines furnished by Seller or its Affiliates, as applicable, to Buyer with respect to the use of such Retained Names and Marks, and (ii) comply with all applicable Laws (“**Quality Standards**”). Furthermore, from time to time, at Seller’s request, Buyer shall (A) furnish to Seller (or its designee) representative samples of all Product Labeling and Product packaging for the Products and all advertising, marketing, promotional or other materials bearing any of the Retained Names and Marks to evaluate Buyer’s compliance with the foregoing Quality Standards, and (B) use commercially reasonable efforts to promptly make any changes to the Product Labeling, Product packaging and advertising, marketing, promotional or other materials bearing any of the Retained Names and Marks as Seller may reasonably request to achieve compliance with the Quality Standards.

(c) Any and all goodwill generated by the use of the Retained Names and Marks as permitted under this Section 5.14 shall, in each case, inure solely to the benefit of Seller and its Affiliates (or its or their licensors, as applicable), and if Buyer obtains any goodwill, right, title or interest in or to any of the Retained Names and Marks, Buyer shall and hereby does assign, and shall cause its Affiliates and its and their sublicensees to assign, to Seller or its Affiliates (or its or their licensors, as applicable) all such goodwill, rights, title and interests. Buyer shall not, and shall cause its Affiliates not to, use the Retained Names and Marks in any manner that would reasonably be expected to damage or tarnish the reputation of Seller or its Affiliates (or its or their licensors, as applicable) or the goodwill associated with the Retained Names and Marks, or take any action that would reasonably be expected to adversely affect Seller’s or its Affiliates’ (or its or their licensor(s)’) rights in any of the Retained Names and Marks or the validity, enforceability or distinctiveness of any of the Retained Names and Marks or any registrations or applications therefor.

5.14.3 Responsibility for Use of Retained Names and Marks. Buyer agrees that none of Seller or its Affiliates (or any of its or their licensors) shall have any responsibility for claims by Third Parties arising out of, or relating to, the use by Buyer or its Affiliates of any Retained Names and Marks. In addition to any and all other available remedies (including those under Article 7), Buyer shall indemnify Seller Indemnitees from and against, and compensate and reimburse them for, any and all such Losses that may arise out of the use of the Retained Names and Marks (a) in connection with the Product Business in accordance with the terms and conditions of this Section 5.14, other than such claims that the use of the Retained Names and Marks in connection with the Product Business in accordance with the terms and conditions of this Section 5.14 infringes or misappropriates the Intellectual Property Rights of any Third Party; or (b) by Buyer or any of its Affiliates in violation of or outside the scope permitted by this Section 5.14; *provided*, that, with respect to any such claim that is asserted by a Third Party, Seller shall have the right in its sole discretion to assume and control the defense, appeal or settlement thereof, with counsel of Seller’s own choice. Notwithstanding anything in this Agreement to the contrary, Buyer hereby acknowledges and agrees that in the event of any breach or threatened breach of this Section 5.14, Seller, in addition to any other remedies available to it, (x) shall be entitled to seek a preliminary injunction, temporary restraining order or other equitable relief restraining Buyer and any of its Affiliates from any such breach or threatened breach and (y) shall not be required to provide any bond or other security in connection with any such injunction, order or other relief. For the avoidance of doubt, except to the extent inconsistent with this Section 5.14.3, the indemnification procedures set forth in Section 7.2 shall apply to this Section 5.14.3.

5.14.4 Destruction and Disposal. Following the end of the Applicable Transition Period for the finished Product in the Purchased Inventory, Buyer shall be solely responsible for (including the cost of) the destruction and disposal of any remaining units of finished Product (i) then in Seller's or any of its Affiliates' possession, and (ii) bearing any NDC number of Seller or any of its Affiliates or any Retained Names and Marks and of any Product Labeling or Product packaging containing any NDC number of Seller or any of its Affiliates or any Retained Names and Marks.

5.15 Non-Competition. Seller hereby agrees that, subject to Section 5.16, Seller and its subsidiaries shall not, directly or indirectly, either for itself or through any other Person, engage in, or otherwise knowingly assist any Person engaging in, the (a) development for distribution and sale in the Territory, (b) Manufacture worldwide for Exploitation in the Territory or (c) distribution or sale in the Territory of any (i) pharmaceutical product with the same active ingredient as a Product, for a period of [***] years following the Closing Date, or (ii) pharmaceutical product with the same approved indication as a Product as of the date hereof, for a period commencing on the Closing Date and expiring on the expiration of the term of Patent No. [***], but no later than June 8, 2026 provided that nothing in this clause (ii) shall prohibit the conduct of Early Research and Development (a pharmaceutical product described in the preceding clauses (a) or (b), a "**Competing Product**"). For the purposes of this Section 5.15, "**Early Research and Development**" shall mean [***].

5.16 Unauthorized Sales.

5.16.1 Following the Closing Date, subject to Section 5.17, Buyer (a) shall cause its Affiliates to, and shall contractually require its licensees, sublicensees and distributors to, distribute, market, promote, offer for sale and sell the Products only in the Territory, and (b) shall not and shall cause its Affiliates not to distribute, market, promote, offer for sale or sell, and shall contractually prohibit its licensees, sublicensees or distributors from, distributing, marketing, promoting, offering for sale or selling, the Product directly or indirectly to any Person outside of the Territory. Buyer shall use commercially reasonable efforts to enforce its contractual rights in the event of any breach of any such contractual requirement or prohibition.

5.16.2 Following the Closing Date, subject to Section 5.17, Seller (a) shall cause its Affiliates to, and shall contractually require its licensees, sublicensees and distributors to, distribute, market, promote, offer for sale and sell the Products only outside the Territory, and (b) shall not and shall cause its Affiliates not to distribute, market, promote, offer for sale or sell, and shall contractually prohibit its licensees, sublicensees or distributors from, distributing, marketing, promoting, offering for sale or selling, the Products directly or indirectly to any Person inside of the Territory. Seller shall use commercially reasonable efforts to enforce its contractual rights in the event of any breach of any such contractual requirement or prohibition.

5.17 Incidental Crossover within Territories. [***].

5.18 Insurance. As of the Closing Date, Buyer shall have and maintain adequate insurance coverage, which policies shall be in effect for so long as Buyer is Exploiting a Product in the Territory and shall include products liability coverage of not less than [***] and comprehensive general liability insurance of not less than [***]; *provided*, that if any such policy is held on a claims-made basis, such policy shall be maintained for so long as Buyer is Exploiting a Product in the Territory and for a period of two years thereafter. All insurers providing such policies shall have an AM Best (A-) or higher rating. Buyer shall provide Seller with certificates of insurance evidencing that the policies required to be maintained by Buyer hereunder are in full force and effect annually and, upon Seller's request, copies of such policies shall be provided. Should any of the policies be cancelled, terminated or otherwise materially altered before the expiration date thereof, notice will be delivered in accordance with the policy provisions in writing to Seller.

5.19 Employee Matters.

5.19.1 [***].

5.19.2 [***].

5.19.3 [***].

**ARTICLE 6
CONDITIONS PRECEDENT**

6.1 Conditions to Obligations of Buyer and Seller. The obligations of Buyer and Seller to complete the Transactions are subject to the satisfaction at or prior to the Closing of the following conditions:

6.1.1 No Adverse Law; No Injunction. No Law shall have been enacted, entered, promulgated or enforced by any Governmental Authority that prohibits the consummation of all or any part of the Transactions, and no order by any Governmental Authority restraining, enjoining or otherwise preventing the consummation of the Transactions shall be in effect; and

6.1.2 Governmental Approvals. All required Authorizations of, notifications to and filings with any Governmental Authority shall have been received or made, as applicable and any waiting period applicable to the Transactions under the HSR Act (and any extension thereof, including under any agreement between a party and a Governmental Authority agreeing not to consummate the Transactions prior to a certain date) shall have expired or been terminated.

6.2 Conditions to Obligations of Buyer. The obligation of Buyer to complete the Transactions is subject to the satisfaction or waiver by Buyer at or prior to the Closing of the following additional conditions:

6.2.1 Representations and Warranties. The representations and warranties of Seller contained in Section 3.1, other than the Fundamental Representation made by Seller, shall be true and correct in all respects (disregarding all "material," "in all material respects" and "Material Adverse Effect" qualifiers) at and as of the Closing Date as if made at and as of such date (except that those representations and warranties that address matters only as of a particular date need only be true and correct as of such date), except for breaches of such representations and warranties that would not, individually or in the aggregate, have a Material Adverse Effect; and the Fundamental Representations made by Seller shall be true and correct in all material respects at and as of the Closing Date as if made at and as of such date (except that those representations and warranties that address matters only as of a particular date need only be true and correct in all material respects as of such date);

6.2.2 Covenants. Seller shall have performed and complied in all material respects with all covenants, agreements and obligations required to be performed or complied with on or prior to the Closing Date;

6.2.3 Material Adverse Effect. Since the date hereof, there shall not have been a Material Adverse Effect; and

6.2.4 Closing Deliveries. Seller shall have delivered to Buyer each of the items listed in Section 2.4.2(a).

6.3 Conditions to Obligations of Seller. The obligation of Seller to complete the Transactions is subject to the satisfaction or waiver by Seller at or prior to the Closing of the following additional conditions:

6.3.1 Representations and Warranties. The representations and warranties of Buyer contained in Section 3.2, other than the Fundamental Representations made by Buyer, shall be true and correct in all respects (disregarding all “material”, “in all material respects” and “Buyer Material Adverse Effect” qualifiers) at and as of the Closing Date as if made at and as of such date (except that those representations and warranties that address matters only as of a particular date need only be true and correct as of such date), except for breaches of such representations and warranties that would not, individually or in the aggregate, reasonably be expected to have a Buyer Material Adverse Effect; the Fundamental Representations made by Buyer, other than the representations and warranties of Buyer set forth in Section 3.2.7 (*Financial Capacity*), shall be true and correct in all material respects at and as of the Closing Date as if made at and as of such date; and the representations and warranties of Buyer set forth in Section 3.2.7 (*Financial Capacity*), shall be true and correct in all respects at and as of the Closing Date as if made at and as of such date;

6.3.2 Covenants. Buyer shall have performed and complied in all material respects with all covenants, agreements and obligations required to be performed or complied with on or prior to the Closing Date; and

6.3.3 Closing Deliveries. Buyer shall have delivered to Seller each of the items listed in Section 2.4.2(b).

6.4 Frustration of Closing Conditions. With respect to the conditions to Buyer’s and Seller’s respective obligations to consummate the Transactions as provided hereunder and each Party’s right to terminate this Agreement as provided in Section 8.1, neither Buyer nor Seller may rely on the failure of any condition set forth in this Article 6 to be satisfied if such failure was caused by such Party’s failure to act in good faith or to use its reasonable best efforts to cause the condition to be satisfied to the extent required by Section 4.4.

**ARTICLE 7
INDEMNIFICATION**

7.1 Indemnification.

7.1.1 Indemnification by Seller. Subject to the provisions of this Article 7, from and after the Closing, Seller shall indemnify, defend and hold harmless Buyer and its Affiliates, and their respective officers, directors, and employees (collectively, “**Buyer Indemnitees**”) from and against, and compensate and reimburse the Buyer Indemnitees for, any and all Losses actually incurred by any Buyer Indemnitee arising out of:

(a) any breach of any of the representations or warranties made by Seller in Section 3.1 or in the certificate delivered by Seller pursuant to Section 2.4.2(a)(ii); *provided*, that all materiality qualifications (such as “material” and “Material Adverse Effect”) in such representations and warranties shall be disregarded for the purposes of this Article 7, including in connection with determining whether a breach has occurred and the amount of Losses incurred;

(b) any failure of Seller to perform or any breach by Seller of any of its covenants, agreements or obligations contained in this Agreement; or

(c) any Excluded Liability.

7.1.2 Indemnification by Buyer. Subject to the provisions of this Article 7, from and after the Closing, Buyer shall indemnify, defend and hold harmless Seller and its Affiliates, and their respective officers, directors, and employees (collectively, “**Seller Indemnitees**”) from and against, and compensate and reimburse Seller Indemnitees for, any and all Losses actually incurred by any Seller Indemnitee arising out of:

(a) any breach of any of the representations or warranties made by Buyer in Section 3.2 or Section 3.3 or in the certificate delivered by Buyer pursuant to Section 2.4.2(b)(iii); *provided*, that all materiality qualifications (such as “material” and “Material Adverse Effect”) in such representations and warranties shall be disregarded for the purposes of this Article 7, including in connection with determining whether a breach has occurred and the amount of Losses incurred;

(b) any failure of Buyer to perform or any breach by Buyer of any of its covenants, agreements or obligations contained in this Agreement; or

(c) any Assumed Liability.

7.2 Claim Procedure.

7.2.1 Indemnification Claim Procedure. [***].

7.2.2 Third Party Claim Procedure.

(a) [***].

(b) [***].

7.2.3 [*]**

7.3 Limitations on Indemnification.

7.3.1 The provisions for indemnity under Section 7.1.1(a) or Section 7.1.2(a) shall be effective only (a) for any individual claim or series of related claims arising from the same facts and circumstances where the Loss exceeds \$[***] and (b) except in the case of fraud or claims for breach of any Fundamental Representation, when the aggregate amount of all Losses for claims or series of related claims arising from the same facts and circumstances in excess of \$[***] for which indemnification is sought from any Indemnifying Party exceeds \$[***] (the “**Deductible**”), in which case the Indemnified Party shall be entitled to indemnification of the Indemnified Party’s Losses in excess of the Deductible. Notwithstanding anything herein to the contrary, no Party shall be liable for any Loss to the extent arising from (i) a change in accounting or Tax Law, policy or practice made after the Closing, other than a change required to comply with any Law, policy or practice in effect on the date hereof, (ii) any Law not in force on the date hereof or any change in Law which takes effect retroactively or (iii) any increase in the rates of taxation in force on the date hereof.

7.3.2 Except for with respect to claims for breach of fraud or any Fundamental Representation, in no event shall any Indemnifying Party have liability for indemnification under (i) Section 7.1.1(a) (other than for claims arising under Section 3.1.10 or Section 3.1.11) or Section 7.1.2(a), as applicable, for any amount exceeding, in the aggregate, \$[***] and (ii) Section 7.1.1(a) (for claims arising under Section 3.1.10 or Section 3.1.11) for any amount exceeding, in the aggregate, \$[***].

7.3.3 In no event shall Seller’s aggregate liability under this Article 7 exceed [***].

7.3.4 The Indemnified Party shall take all commercially reasonable steps to mitigate any Losses incurred by such party upon and after becoming aware of any event or condition that would reasonably be expected to give rise to any indemnification rights hereunder. The amount of Losses recovered by an Indemnified Party under Section 7.1.1 or Section 7.1.2, as applicable, shall be reduced by (a) any amounts actually recovered by the Indemnified Party from a Third Party in connection with such claim, (b) the amount of any insurance proceeds paid to the Indemnified Party relating to such claim and (c) any Tax benefit actually realized by the Indemnified Party arising from such Losses in the Tax year of such Loss or the next succeeding Tax year, determined on a “with and without” basis. If any amounts referenced in the preceding clauses (a) and (b) are received after payment by the Indemnifying Party of the full amount otherwise required to be paid to an Indemnified Party pursuant to this Article 7, the Indemnified Party shall repay to the Indemnifying Party, promptly after such receipt, any amount that the Indemnifying Party would not have had to pay pursuant to this Article 7 had such amounts been received prior to such payment.

7.3.5 The representations and warranties of Seller and Buyer contained in this Agreement and the covenants and agreements of the Parties set forth in Article 4 shall survive the Closing and continue in full force and effect thereafter through and including the date that is [***] months after the Closing Date; *provided*, that the Fundamental Representations shall remain in full force and effect and shall survive until 60 days following the expiration of the applicable statute of limitations (excluding any extension under Section 8106(c) of Title 10 of the Delaware Code). Except as otherwise provided in this Agreement, the covenants and agreements contained in this Agreement (other than in Article 4) shall survive the Closing and continue in full force and effect thereafter until fully performed in accordance with this Agreement; *provided, however*, that Seller's obligations under Section 7.1.1 with respect to any Seller Product Liability Claim shall expire on the fifth anniversary of the Closing Date. If a Claim Notice or Indemnification Certificate relating to any matter for which indemnification is provided under this Article 7 is given to the Indemnifying Party on or prior to the date on which the applicable survival period described in this Section 7.3.5 expires, then, notwithstanding anything to the contrary contained in this Section 7.3.5, such Claim Notice or Indemnification Certificate, as applicable, shall not expire at the applicable expiration date, but rather shall remain in full force and effect until such time as the Claim Notice or the Indemnification Certificate has been fully and finally resolved.

7.3.6 TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW AND EXCEPT AS A RESULT OF FRAUD, FROM AND AFTER THE CLOSING, NEITHER BUYER NOR SELLER SHALL BE LIABLE TO THE OTHER, OR THEIR AFFILIATES, FOR ANY CLAIMS, DEMANDS OR SUITS FOR CONSEQUENTIAL, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE, INDIRECT OR MULTIPLE DAMAGES, LOSS OF PROFITS, REVENUE OR INCOME, DIMINUTION IN VALUE OR LOSS OF BUSINESS OPPORTUNITY (WHETHER OR NOT FORESEEABLE AT THE CLOSING DATE) CONNECTED WITH OR RESULTING FROM ANY BREACH OF THIS AGREEMENT, OR ANY ACTIONS UNDERTAKEN IN CONNECTION HERewith, OR RELATED HERETO, INCLUDING ANY SUCH DAMAGES THAT ARE BASED UPON BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE AND MISREPRESENTATION), BREACH OF WARRANTY, STRICT LIABILITY, STATUTE, OPERATION OF LAW OR ANY OTHER THEORY OF RECOVERY.

7.3.7 For the avoidance of doubt, no Indemnified Party shall be entitled to indemnification under this Article 7 in respect of any Loss to the extent such Indemnified Party has been previously indemnified or reimbursed in respect of such Loss pursuant to any other provision of this Agreement or any provision of any Ancillary Agreement.

7.4 Tax Treatment of Indemnification Payments. All payments made pursuant to this Article 7 shall be treated as adjustments to the Purchase Price for all Tax purposes, unless otherwise required by applicable Law.

7.5 Exclusive Remedy. Except as expressly provided otherwise in this Agreement (including Section 2.3.2, Section 2.5.4 and Section 5.14.3), subject to Section 9.10 and, except in the case of fraud, each Party acknowledges and agrees that from and after the Closing the remedies provided for in this Article 7 shall be the sole and exclusive remedies for claims and damages available to the Parties and their respective Affiliates arising out of or relating to this Agreement and the transactions contemplated hereby, including the negotiation of this Agreement, any alleged non-disclosure or misrepresentations made hereunder and Buyer's and its Affiliates' due diligence investigation with respect to the transactions contemplated hereby. Notwithstanding anything to the contrary contained in this Agreement, no breach of any representation, warranty, covenant or agreement contained herein, shall, after the consummation of the transactions contemplated by this Agreement, give rise to any right on the part of Buyer, on the one hand, or Seller, on the other hand, to rescind this Agreement or any of the transactions contemplated hereby. No past, present or future director, officer, employee, incorporator, manager, member, partner, stockholder, Affiliate, agent, attorney or other Representative of a Party or of any Affiliate of a Party, or any of their successors or permitted assigns, shall have any liability for any obligations or liabilities of a Party under this Agreement or for any claim, action, suit or other legal proceeding based on, in respect of or by reason of the transactions contemplated hereby. For purposes of this Agreement, "**fraud**" means with respect to any Party, the knowing and intentional misrepresentation of material fact in the making of any representation or warranty of such Party in this Agreement with the intent to mislead or deceive the other Party in a manner that constitutes common law fraud under Delaware Law. This Section 7.5 shall not affect either Party's or any Affiliate of either Party's ability to exercise any rights or remedies available to such Person under any Ancillary Agreement with respect to claims arising under such Ancillary Agreement.

7.6 Setoff Rights. Neither Party shall have any right of setoff of any amounts due and payable, or any Liabilities arising under this Agreement against any other amounts due and payable under this Agreement or any amounts due and payable, or any Liabilities arising, under any Ancillary Agreement. The payment obligations under each of this Agreement and the Ancillary Agreements remain independent obligations of each Party, irrespective of any amounts owed to any other Party under this Agreement or the respective Ancillary Agreements.

ARTICLE 8 TERMINATION

8.1 Termination. Prior to the Closing, this Agreement shall terminate on the earliest to occur of any of the following events:

8.1.1 the mutual written agreement of Buyer and Seller;

8.1.2 by written notice delivered by either Buyer or Seller to the other, if the Closing shall not have occurred on or prior to March 17, 2023 (the "**End Date**") (other than due to a breach of any representation or warranty hereunder of the Party seeking to terminate this Agreement or as a result of the failure on the part of such Party to comply with or perform any of its covenants, agreements or obligations under this Agreement); *provided*, that neither Party shall have the right to terminate this Agreement under this Section 8.1.2 during the pendency of any Litigation commenced under Section 9.10 to compel the Closing;

8.1.3 by written notice delivered by Buyer to Seller, if (a) there has been a breach by Seller of a representation or warranty of Seller contained in this Agreement or (b) there shall be a material breach by Seller of any covenant, agreement or obligation of Seller in this Agreement, and such failure or breach described in clause (a) or (b) would result in the failure of a condition set forth in Section 6.2.1 or Section 6.2.2 that has not been waived by Buyer, or in the case of a breach of any covenant or agreement, is not cured upon the earlier to occur of (i) the 30th day after written notice thereof is given by Buyer to Seller and (ii) the day that is two Business Days prior to the End Date; *provided*, that Buyer may not terminate this Agreement pursuant to this Section 8.1.3 if Buyer is in breach of any of its representations, warranties, agreements or covenants contained in this Agreement and such breach would result in the failure of a condition set forth in Section 6.3.1 or Section 6.3.2; or

8.1.4 by written notice delivered by Seller to Buyer, if (x) (a) there has been a breach by Buyer of a representation or warranty of Buyer contained in this Agreement or (b) there shall be a material breach by Buyer of any covenant, agreement or obligation of Buyer in this Agreement, and such failure or breach described in clause (a) or clause (b) would result in the failure of a condition set forth in Section 6.3.1 or Section 6.3.2 and has not been waived by Seller, or in the case of a breach of any covenant or agreement, is not cured upon the earlier to occur of (i) the 30th day after written notice thereof is given by Seller to Buyer and (ii) the day that is two Business Days prior to the End Date; *provided*, that Seller may not terminate this Agreement pursuant to this Section 8.1.4 if Seller is in breach of any of its representations, warranties, agreements or covenants contained in this Agreement and such breach would result in the failure of a condition set forth in Section 6.2.1 or Section 6.2.2; or (y) notwithstanding any cure periods set forth in Section 8.1.4(x), if all of the conditions set forth in Section 6.1 and 6.2 have been satisfied (other than any condition which by its nature is to be satisfied at the Closing) and Buyer fails to consummate the Closing by the time the Closing should have occurred pursuant to Section 2.4.1.

8.2 Procedure and Effect of Termination.

8.2.1 Notice of Termination. Termination of this Agreement by either Buyer or Seller shall be by delivery of a written notice to the other. Such notice shall state the termination provision in this Agreement that such terminating Party is claiming provides a basis for termination of this Agreement. Termination of this Agreement pursuant to the provisions of Section 8.1 shall be effective upon and as of the date of delivery of such written notice as determined pursuant to Section 9.2.

8.2.2 Effect of Termination. In the event of the termination of this Agreement pursuant to Section 8.1 by Buyer or Seller, this Agreement shall be terminated and have no further effect, except that Sections 5.3 (*Publicity*), 5.4 (*Confidentiality*), 8.2.2 (*Effect of Termination*), 8.2.3 (*Withdrawal of Certain Filings*) and Article 9 (*Miscellaneous*) shall survive any termination of this Agreement and there shall be no liability hereunder on the part of Seller, Buyer or any of their respective Affiliates, except (a) as liability may exist pursuant to the Sections or Articles specified in this Section 8.2.2 that survive such termination, and (b) that no such termination shall relieve a Party from any liability arising out of any Willful Breach by such Party of any representation, warranty, covenant or agreement of such Party contained herein prior to such termination or fraud. “**Willful Breach**” means a deliberate act or a deliberate failure to act, which act or failure to act constitutes in and of itself a material breach of this Agreement with the actual knowledge that the taking of such act or failure to take such action would be a material breach of this Agreement. For clarity, in the event of termination of this Agreement pursuant to Section 8.1, the Parties shall not enter into any of the Ancillary Agreements not entered into on the date hereof or have any obligations thereunder.

8.2.3 Withdrawal of Certain Filings. As soon as practicable following a termination of this Agreement for any reason, but in no event less than 30 days after such termination, Buyer or Seller shall, to the extent practicable, withdraw all filings, applications and other submissions relating to the Transactions filed or submitted by or on behalf of such Party, any Governmental Authority or other Person.

**ARTICLE 9
MISCELLANEOUS**

9.1 Governing Law, Jurisdiction, Venue and Service.

9.1.1 Governing Law. This Agreement, and all Disputes that may be based upon, arise out of or relate to this Agreement, or the negotiation, execution or performance of this Agreement (including any Dispute 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), will be governed by, and enforced and construed in accordance with, the Law of the State of Delaware, including its statutes of limitations, without regard to the conflict of Laws rules of such state that would result in the application of the Laws of another jurisdiction.

9.1.2 Jurisdiction; Jury Trial Waiver. Subject to Section 9.10, the Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of the Delaware Court of Chancery and the United States District Court for the District of Delaware sitting in New Castle County for any Dispute, action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement, and agree not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such courts. EACH PARTY HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT TO ANY LITIGATION DIRECTLY OR INDIRECTLY ARISING OUT OF, UNDER OR IN CONNECTION WITH THIS AGREEMENT OR THE TRANSACTIONS OR DISPUTES RELATING HERETO. EACH PARTY (a) CERTIFIES THAT NO REPRESENTATIVE OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER AND (b) ACKNOWLEDGES THAT IT AND THE OTHER PARTY HAVE BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 9.1.2.

9.1.3 Venue. The Parties further hereby irrevocably and unconditionally waive any objection to the laying of venue of any Dispute, action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement in the Delaware Court of Chancery or in the United States District Court for the District of Delaware sitting in New Castle County, and hereby further irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.

9.1.4 Service. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 9.2.2 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such court.

9.2 Notices.

9.2.1 Notice Requirements. Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement (each, a “**Notice**”) shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if delivered by hand or sent by facsimile transmission or by email of a PDF (or similar electronic) attachment (with transmission confirmed) or by overnight registered mail, courier or express delivery service that maintains records of delivery, addressed to the applicable Party at its address specified in Section 9.2.2 or to such other address as the Party to whom notice is to be given may have provided to the other Party at least 10 days prior to such address taking effect in accordance with this Section 9.2. Such Notice shall be deemed to have been received: (a) as of the date delivered by hand or by overnight registered mail, courier or express delivery service; or (b) on the day sent by facsimile or email, *provided* that the sender has received confirmation of transmission (by facsimile or email receipt confirmation or confirmation by telephone or, with respect to facsimile only, email) prior to 6:00 p.m. Eastern Time on such day (and if confirmation is received after 6:00 p.m. Eastern Time, such Notice shall be deemed to have been delivered on the following Business Day).

9.2.2 Address for Notice.

If to Seller, to:

Eisai Co., Ltd.
4-6-10 Koishikawa
Bunkyo-ku, Tokyo
112-8088 Japan
Email: [***]
Attention: General Counsel

with a copy (which shall not constitute notice) to:

Eisai Inc.
200 Metro Boulevard
Nutley, NJ 07110
Attention: General Counsel

with a copy (which shall not constitute notice) to:

Covington & Burling LLP
One CityCenter
850 Tenth Street, N.W.
Washington, DC 20001
Email: mriella@cov.com
Attention: Michael J. Riella

If to Buyer, to:

Catalyst Pharmaceuticals, Inc.
355 Alhambra Circle, Suite 801
Coral Gables, FL 33134
Attention: General Counsel

with a copy (which shall not constitute notice) to:

Akerman LLP
201 East Las Olas Blvd., 18th Floor
Fort Lauderdale, FL 33301
Attention: Philip B. Schwartz, Esq.

Cooley (UK) LLP 22 Bishopsgate
London EC2N 4BQ
United Kingdom
Attention: Michal Berkner
Frances Stocks Allen
Email: mberkner@cooley.com
fstocksallen@cooley.com

9.3 No Benefit to Third Parties. The covenants and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and, except for the rights of Seller Indemnitees under Section 5.14.3 and the rights of the Buyer Indemnitees and Seller Indemnitees under Article 7, they shall not be construed as conferring any rights on any other Persons.

9.4 Relationship of the Parties. Nothing contained in this Agreement shall be deemed or construed to create a partnership, joint venture, employment, franchise, agency or fiduciary relationship between Buyer and Seller. Neither Party shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement or undertaking with any Third Party.

9.5 Waiver. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by any Party of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.

9.6 Expenses. Except as otherwise specified herein or in any Ancillary Agreement, and whether or not the Closing takes place, each Party shall bear any costs and expenses incurred by it with respect to the Transactions.

9.7 Assignment. Neither this Agreement nor either Party's rights or obligations hereunder may be assigned or delegated by such Party without the prior written consent of the other Party, and any attempted assignment or delegation of this Agreement or any of such rights or obligations by either Party without the prior written consent of the other Party shall be void and of no effect; *provided, however*, (i) either Party may assign or delegate any or all of its rights or obligations hereunder to an Affiliate without the prior written consent of the other Party and (ii) following the termination or expiration of all Services other than the Manufacturing Services and the Post-Marketing Study Services under (and as defined in) the Transition Services Agreement, Buyer may transfer this Agreement to a direct or indirect purchaser of the Products and the Product Business without the prior written consent of Seller, *provided further*, that in each case (clauses (i) and (ii)), no such assignment shall relieve the assigning Party of any of its obligations under this Agreement. Subject to the preceding sentence, this Agreement will be binding upon, inure to the benefit of, and be enforceable by, the Parties and their respective successors and permitted assigns. Notwithstanding the foregoing, in the event a Party assigns its rights or obligations under this Agreement or otherwise makes payments from a jurisdiction other than the jurisdiction in which such party is organized (each an "**Assignment**"), and immediately after such Assignment the amount of Tax required to be withheld on any payment pursuant to this Agreement is greater than the amount of such Tax that would have been required to have been withheld absent such Assignment, then such increased withholding Tax shall be borne by the Party making such Assignment.

9.8 Amendment. This Agreement may not be modified, amended, altered or supplemented except upon the execution and delivery of a written agreement executed by both Parties.

9.9 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future Law, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties.

9.10 Equitable Relief. The Parties agree that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached. It is accordingly agreed that (a) either Party shall be entitled to an injunction or injunctions, specific performance or other equitable relief to prevent breaches or threatened breaches of this Agreement and to enforce specifically the terms and provisions hereof in any court of competent jurisdiction without proof of damages or otherwise, this being in addition to any other remedy to which it is entitled under this Agreement, at law or in equity, and (b) the right of specific enforcement is an integral part of the Transactions and without that right, no Party would have entered into this Agreement. Each Party hereby waives (i) any requirement that the other Party post a bond or other security as a condition for obtaining any such relief, and (ii) any defenses in any action for specific performance, including the defense that a remedy at law would be adequate.

9.11 English Language. This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

9.12 Bulk Sales Statutes. Buyer hereby waives compliance by Seller with any applicable bulk sales Laws in any jurisdiction in connection with the transactions under this Agreement.

9.13 Counterparts. This Agreement may be executed in any number of counterparts and manually or electronically, and each such counterpart hereof shall be deemed to be an original instrument, but all such counterparts together shall constitute but one agreement. Delivery of an executed counterpart of a signature page of this Agreement by electronic transmission shall be effective as delivery of a manually executed original counterpart of this Agreement.

9.14 Entire Agreement. This Agreement, together with the Schedules and Exhibits expressly contemplated hereby and attached hereto, the Disclosure Schedules, the Ancillary Agreements, the Confidentiality Agreement and the other agreements, certificates and documents delivered in connection herewith or therewith or otherwise in connection with the Transactions, contain the entire agreement between the Parties with respect to the Transactions and supersede all prior agreements, understandings, promises and representations, whether written or oral, between the Parties with respect to the subject matter hereof and thereof.

[Signature page follows]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first written above.

EISAI CO., LTD.

By: /s/ Mitsuo Kosaka

Name: Mitsuo Kosaka

Title: Chief Strategy Officer

CATALYST PHARMACEUTICALS, INC.

By: /s/ Patrick J. McEnany

Name: Patrick J. McEnany

Title: Chairman, President and CEO

[SIGNATURE PAGE TO ASSET PURCHASE AGREEMENT]

Certain identified information has been excluded from this exhibit because it is both (i) not material, and (ii) would likely cause competitive harm to the registrant if publicly disclosed. [***] indicates that information has been redacted.

EXHIBIT J

FORM OF TRANSITION SERVICES AGREEMENT

TRANSITION SERVICES AGREEMENT

by and between

Eisai Inc.

and

Catalyst Pharmaceuticals, Inc.

Dated as of [•]

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TRANSITION SERVICES AGREEMENT

This Transition Services Agreement (this “**Agreement**”) dated as of [•] (the “**Effective Date**”), by and between Eisai Inc., a Delaware corporation (“**Seller**”) and Catalyst Pharmaceuticals, Inc., a Delaware corporation (“**Buyer**”). Seller and Buyer are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**”.

WHEREAS, Eisai Co., Ltd., the parent company of Seller, and Buyer are parties to that certain Asset Purchase Agreement, dated as of December 17, 2022 (the “**Asset Purchase Agreement**”), pursuant to which Buyer has agreed to purchase from Seller the Purchased Assets (as defined in the Asset Purchase Agreement); and

WHEREAS, following the consummation of the transactions contemplated by the Asset Purchase Agreement, Seller has agreed to perform certain Services for certain periods after the Effective Date for the benefit of Buyer and its Affiliates with respect to Buyer’s operation of the Product Business (as defined in the Asset Purchase Agreement) during such periods, subject to the terms and conditions contained herein, which the Parties acknowledge have been negotiated on an arms’ length basis by Buyer and Seller.

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions hereinafter set forth, and set forth in the Asset Purchase Agreement and the other Ancillary Agreements (as defined in the Asset Purchase Agreement), and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

ARTICLE 1 DEFINITIONS

1.1 Certain Defined Terms. Unless otherwise specifically provided herein, capitalized and other terms used, but not otherwise defined, herein shall have the meanings ascribed thereto in the Asset Purchase Agreement. As used herein, the following terms have the following meanings.

“**Auditor**” means an accounting firm of international reputation (excluding each of Seller’s and its Affiliates and Buyer’s and its Affiliates’ respective regular outside accounting firms) as may be mutually acceptable to Seller and Buyer (each acting reasonably); *provided, however*, if Seller and Buyer are unable to agree on such accounting firm within 10 days after a need to engage the Auditor arises under this Agreement or any such mutually selected accounting firm is unwilling or unable to serve, then Seller shall deliver to Buyer a list of three other accounting firms of international reputation that have not performed services for Seller or its Affiliates or Buyer or its Affiliates in the preceding three-year period, and Buyer shall select one of such three accounting firms.

“**Branded Prescription Drug Fees**” or “**BPD Fees**” means the fees described in Section 9008 of the Patient Protection and Affordable Care Act, as amended by Section 1404 of the Health Care and Education Reconciliation Act of 2010.

“**Calendar Quarter**” means the respective periods of three consecutive calendar months ending on March 31, June 30, September 30 and December 31, except that, other than for purposes of Article 3, (a) the first Calendar Quarter under this Agreement shall commence on the Effective Date and end on the first March 31, June 30, September 30 or December 31 to occur after the Effective Date and (b) the last Calendar Quarter under this Agreement shall commence on the last January 1, April 1, July 1 or October 1 to occur prior to the expiration of the Transition Period and end on the date of expiration of the Transition Period.

“**CMS**” means Centers for Medicare and Medicaid Services within the United States Department of Health and Human Services, or any successor organization or agency.

“**Customers**” means Third Party wholesalers, pharmacy benefit managers, managed care organizations, government buyers, or any other Third Parties that contract with Seller or any of its Affiliates with respect to the utilization of any Product or purchase any Product from Seller or any of its Affiliates, in each case in the Territory, as of the Effective Date.

“**Cutover Date**” means the date that is [***] or such other date as Seller and Buyer agree upon in writing.

“**Excluded Services**” means all services other than the Services.

“**Finished Product**” means a Product in finished, packaged form, labeled for sale in the Territory.

“**FSS**” means the Federal Supply Schedule administered by the United States Department of Veterans Affairs.

“**Government Contract**” means any prime contract, subcontract, letter contract, purchase order or delivery order executed or submitted to or on behalf of any Governmental Authority in the Territory or any prime contractor or higher-tier subcontractor in the Territory, or under which any such Governmental Authority or any such prime contractor or subcontractor otherwise has or may acquire any right or interest.

“**Indirect Taxes**” means value added taxes, sales taxes, consumption taxes and other similar Taxes that are required to be disclosed on an Indirect Tax invoice.

“**Invoice Date**” means the date of the wholesaler’s invoice for the sale of Product to the end user.

“**Labeler Code**” means the four or five digit code assigned to the manufacturer or distributor of drug products by the FDA included as the first four or five digits of the NDC number for the products Manufactured or distributed by such Person.

“**Medicaid Rebate Program**” means the rebate program established pursuant to 42 U.S.C. §1396r-8.

“**Medicare Part D Coverage Gap Discounts**” means Rebates under the Rebate program codified at 42 U.S.C. § 1395w-114a.

“**Medicare Part D Prescription Drug Plan**” means a prescription drug plan that has been approved by CMS to offer prescription drug coverage that is either integrated with health care coverage provided under Part C of the Medicare Program to enrollees or a stand-alone Part D drug plan, codified at 42 U.S.C. §§ 1395w-101, *et seq.*

“**Medicare Program**” means the program established pursuant to 42 U.S.C. Subchapter XVIII.

“**Net Margin Amount**” means, for a Calendar Quarter, the amount equal to [***].

“**NFAMP**” means the non-federal average manufacturer price as defined in 38 U.S.C. §8126.

“**Out-of-Pocket Costs**” means, to the extent documented: [***].

“**PDUFA Fees**” means all fees payable with respect to the Products under the Prescription Drug User Fee Act.

“**PHS 340B Program**” means the drug discount program, available to “covered entities,” that is administered by the Health Resources and Services Administration pursuant to 42 U.S.C. §256B.

“**Rebate Tail Period**” means the 35 day period following the Effective Date.

“**Seller-Related Losses**” means Losses to the extent caused by (a) the gross negligence or willful misconduct of Seller or any of its Affiliates or subcontractors in the performance of obligations under, or (b) any breach by Seller or any of its Affiliates or subcontractors of, this Agreement.

“**State Assistance Program**” means any Medicaid supplemental rebate programs, state pharmaceutical assistance programs, and other state programs to provide pharmaceutical assistance for which Seller or any of its Affiliates has entered into a rebate or discount agreement with a state effective prior to the Cutover Date with respect to any Product.

“**Transition Lots**” means those lots of Product identified of Schedule 1.1.

“**Tricare Rebates**” means rebates paid under the Tricare Retail Pharmacy Program as implemented pursuant to 31 C.F.R. 199.

1.2 Construction. Section 1.2 of the Asset Purchase Agreement is hereby incorporated by reference into this Agreement, *mutatis mutandis*.

ARTICLE 2 SERVICES

2.1 Provision of Services.

2.1.1 Subject to the terms and conditions of this Agreement, during the Transition Period, Seller shall (a) provide or cause to be provided to Buyer or its Affiliates the Manufacturing Services, and the services described in Section 2.10.1 (the “**Distribution Services**”), in Section 2.11 (the “**Regulatory/PV Services**”) and on Schedule 2.1(a) (the “**Post-Marketing Study Services**”), and (b) use commercially reasonable efforts to provide or cause to be provided to Buyer or its Affiliates, as designated in writing by Buyer, the transitional services set forth on Schedule 2.1(b) (the “**Transitional Services**”) during such periods as are specified in this Agreement or Schedule 2.1(b), as applicable, as such Transitional Services were being utilized or conducted by Seller in connection with the Product Business in the 12 months prior to the Effective Date, when and as such Transitional Services are reasonably requested by Buyer. The Transitional Services together with the Manufacturing Services, the Distribution Services, the Regulatory/PV Services and the Post-Marketing Study Services shall collectively be referred to as the “**Services**”. For the avoidance of doubt, except with respect to any contracts Buyer enters into as contemplated under Article 3, the Services shall not include implementing or otherwise providing services with respect to any new customer contracts or programs initiated by Buyer during the Transition Period.

2.1.2 Seller shall have no obligation to provide or cause to be provided to Buyer or its Affiliates any Transitional Service not provided or conducted with respect to a Product in the 12 months prior to the Effective Date, and neither Seller nor any of its Affiliates will be required to perform or to cause to be performed any of the Services for the benefit of any Person other than Buyer and its Affiliates. If there is any inconsistency between the terms of Schedule 2.1 and the terms of this Agreement, the terms of this Agreement shall govern. Except as expressly set forth herein, from and after the Effective Date, Seller’s and its Affiliates’ and Buyer’s and its Affiliates’ respective obligations and rights with respect to the Products in the Territory shall be as set forth in the Asset Purchase Agreement or the other applicable Ancillary Agreements. For the avoidance of doubt, the Services do not include, and Seller shall have no obligation to provide, any Excluded Services.

2.1.3 The description of the Services set forth on Schedule 2.1 may be amended from time to time throughout the Transition Period upon the mutual written agreement of the Parties, and any such amendment shall be considered part of this Agreement and incorporated herein by this reference. Any such amendment shall provide an appropriate change in the Services Fee to the extent the scale, scope or duration of any Service is modified.

2.2 Services Performed by Affiliates and Third Parties. Seller shall have the right to perform the Services either itself, through any Affiliate or through any subcontractor; *provided* that Seller shall in all cases remain responsible for the performance of its obligations hereunder, including for the performance and any breach of this Agreement by its Affiliates and subcontractors.

2.3 Services Standard.

2.3.1 [***].

2.3.2 [***].

2.4 Transitional Nature of Services; Changes. Buyer acknowledges and agrees that the Services are intended only to be transitional in nature, and shall be furnished by Seller only during the Transition Period, and solely for the purpose of accommodating Buyer in connection with the transactions contemplated by the Asset Purchase Agreement. Buyer shall ensure that it or its applicable Affiliates will have sufficient resources available at the end of the Transition Period to perform the Services (or have the Services performed) without the involvement of Seller, its Affiliates or any of its or their respective employees or agents. Buyer acknowledges and agrees that Seller or its Affiliates may make changes from time to time in the manner of performing the Services if Seller or its Affiliates (a) are making similar changes in performing similar services for themselves or their own Affiliates, or would have made similar changes in performing similar services for the Product Business, and (b) if applicable, furnish to Buyer substantially the same notice (in content and timing) as Seller or its Affiliates shall furnish, or would have furnished, to their own Affiliates with respect to such changes; *provided* that in the event any such changes would be materially detrimental to Buyer's ability to continue to conduct Product-related activities in the same manner as the Seller conducted its own services related to the Products in the 12 months prior to the Effective Date, the Parties shall negotiate in good faith to develop acceptable alternative work-around arrangements for the provision of the applicable Services.

2.5 Location of Services Provided; Travel Expenses. Seller shall provide the Services to Buyer or its applicable Affiliate from locations of Seller's choice in its sole discretion unless Services are required to be performed at a specific location identified in Schedule 2.1. Should the provision of Services require any personnel of Seller to travel beyond 50 miles from his or her employment location, Buyer shall reimburse Seller for all reasonable, documented, travel-related costs, consistent with Seller's travel policy.

2.6 Transition Management. Within five Business Days after the Effective Date, Buyer and Seller each shall designate an appropriate point of contact for all questions and issues relating to the Services (the "**Transition Managers**"). Each of Seller and Buyer may, by written notice given to the other such Party, replace its Transition Manager in its sole discretion. As soon as reasonably practicable following the Effective Date, the Parties shall commence planning for full transition of all Services to Buyer through the respective Transition Managers and shall designate teams and team leads with respect to each of the functional-related Services. The Transition Managers shall meet at least once per month, or on such other schedule as mutually agreed upon by Seller and Buyer, during the Transition Period in person or telephonically in order to discuss the Services and the status of the transition and to manage any open issues relating to the Services.

2.7 Cooperation. Each of Buyer and Seller shall use commercially reasonable efforts to cooperate with one another in all matters relating to the provision and receipt of the Services. Without limiting the generality of the foregoing sentence:

2.7.1 Buyer shall and shall cause its Affiliates to permit Seller, its Affiliates and its and their respective employees and agents reasonable access during regular business hours (or otherwise upon reasonable prior notice) to such data and personnel as are involved in receiving or overseeing the Services, and records as reasonably requested by Seller to facilitate Seller's performance of this Agreement.

2.7.2 Subject to the last sentence of this Section 2.7.2, Seller and its Affiliates shall be relieved of their obligation to provide a Service if (a) the provision of such Service is dependent or otherwise reliant on Buyer or any of its Affiliates timely providing to Seller or any of its Affiliates or subcontractors any information, materials, products and like items in a manner substantially similar in nature, quality and timeliness to the information, materials, products and like items that Seller or any of its Affiliates supplied to those of its employees and contractors engaged in the Product Business at the time of the Closing and Buyer or its applicable Affiliate, at its sole cost and expense, fails to so provide such information, materials, products and like items during the Transition Period; or (b) Buyer's or its applicable Affiliate's failure to perform its obligations under this Agreement, including providing cooperation as set forth in this Section 2.7, materially hinders or prevents Seller's performance of such obligation. In the event Seller believes that Buyer or its applicable Affiliate has failed to provide any such information, materials, products and like items, the Transition Manager of Seller shall provide notice of such alleged failure to the Transition Manager of Buyer and the Transition Managers shall discuss and work together in good faith to resolve any impact such alleged failure may have to the provision of the Services.

2.8 Consents. [***].

2.9 Exclusions. [***].

2.10 Distribution Services.

2.10.1 Distribution. Buyer hereby appoints Seller as its exclusive distributor of the Products in the Territory during the Transition Period in accordance with the terms and conditions of this Agreement. Seller or its applicable Affiliate shall distribute and sell the Products in the Territory on behalf of Buyer, in the ordinary course of business, until the end of the Transition Period. Buyer shall not, and shall cause its Affiliates, licensees and sublicensees not to, distribute or sell any Product prior to the end of the Transition Period. Buyer shall assume responsibility for distribution and sale of the Products from and after the end of the Transition Period. Until the end of the Transition Period, Seller shall, on behalf of Buyer, continue to process customer orders (including billing and collection) for the Product Business and prepare and ship Finished Product in the Territory in the ordinary course of business.

2.10.2 Net Sales.

(a) [***].

(b) [***].

2.10.3 Inventory Management.

(a) Until distributed and sold by Seller or its applicable Affiliate in accordance with Section 2.10.1 or delivered to Buyer in accordance with Section 2.10.3(b), Seller or its applicable Affiliates shall store (or cause its applicable Third Party contractor to store) the Purchased Inventory on behalf and for the benefit of Buyer. Risk of loss with respect to such Purchased Inventory shall remain with Buyer.

(b) Within five Business Days following the end of the Transition Period, Seller shall make available any remaining quantities of Finished Product held for sale in the Territory in Seller's or its Affiliates' possession or control [***]. Buyer shall pay to Seller in accordance with Article 4 the aggregate Supply Price for any such remaining quantities of Finished Product.

(c) At the expiration or earlier termination of the Initial Transition Period, subject to obtaining all necessary Consents of Third Parties, Seller shall assign, transfer, convey and deliver to Buyer each of the Contracts identified on Schedule 2.10.3(c) to the extent relating to the Products and the Territory (the "**Manufacturing Contracts**"), and Buyer shall accept such Manufacturing Contracts from Seller and assume and pay and discharge when due all Liabilities under each such Manufacturing Contract, in each case to the extent relating to the Products and the Territory and arising following the expiration or earlier termination of the Initial Transition Period or for orders of Products for the Territory placed prior to the expiration or earlier termination of the Initial Transition Period and to be fulfilled by the applicable Third Party after the expiration or earlier termination of the Initial Transition Period. In the event the Consent of a Third Party is required in order to so assign, transfer, convey or deliver a Manufacturing Contract, Section 5.2.2 of the Asset Purchase Agreement shall apply to such Manufacturing Contract *mutatis mutandis*; provided that, notwithstanding anything to the contrary in the Asset Purchase Agreement, if Seller does not deliver at Closing any Third Party consent required to assign the Manufacturing Contracts to Buyer (with such consents providing for a delayed assignment to be effective at the end of the Initial Transition Period), then Seller shall, at its sole cost and expense, take all actions required to obtain any such consent prior to the expiration or earlier termination of the Initial Transition Period. [***]

2.10.4 Product Supply.

(a) During the Transition Period, Seller or its Affiliates shall continue to Manufacture or cause to be Manufactured and supply Finished Product for distribution, sale and sampling purposes in the Territory in accordance with Seller's then-current demand forecast for the Territory (the "**Manufacturing Services**"). [***].

(b) [***].

2.11 Regulatory/PV Services.

2.11.1 [***].

2.11.2 [***].

2.11.3 [***].

2.11.4 [***].

2.11.5 [***].

2.12 Promotion; Coupons and Vouchers.

2.12.1 During the portion of the Transition Period in which Seller is providing the Transitional Services described under the “Commercial” heading on Schedule 2.1(b), neither Buyer nor any of its Affiliates shall conduct any marketing or promotional activities with respect to the Products in the Territory. For clarity, the preceding shall not restrict (a) Buyer’s or its Affiliates’ contracting discussions relating to Product in the Territory or (b) Buyer’s or its Affiliates’ broad-based publicity (such as on Buyer’s website) relating to Product in the Territory, subject to Section 5.3 of the Asset Purchase Agreement.

2.12.2 Seller shall be responsible for processing, in the ordinary course and in accordance with the Services Standard, any coupons or vouchers for the Products in the Territory redeemed by patients during the Transition Period; *provided* that Seller shall, on a monthly basis during the Transition Period, provide the details set forth on Schedule 2.12.2 on such redemptions to Buyer in order to allow Buyer to adequately prepare for post-transition activities. Buyer shall be financially responsible for any and all coupons and vouchers for the Product in the Territory redeemed after the Effective Date. Buyer’s financial responsibility to Seller for such amounts will be settled through the Net Margin Amount calculation during the period in which the Net Margin Amount is payable hereunder. Following such period, Buyer shall reimburse Seller for all coupons and vouchers for any Product in the Territory honored by Seller after the Effective Date, within 30 days following Buyer’s receipt of written invoice and supporting documentation from Seller.

2.13 IND Transfer. Promptly, but no later than 30 days, following the completion of all Post-Marketing Study Services, Buyer and Seller shall (and shall cause their respective Affiliates to) cooperate with one another and use their respective reasonable best efforts to complete, execute and file or cause to be filed with FDA all documentation required to effect the transfer to Buyer or its applicable Affiliate of all INDs held by Seller or any of its Affiliates covering the clinical studies that were the subject of the Post-Marketing Study Services. Each Party shall bear its own costs and expenses in connection with the transfer of such INDs to Buyer or its applicable Affiliate; *provided, however*, that Buyer shall be responsible for the payment of any filing or similar fees payable to the applicable Governmental Authority with respect to the transfer of such INDs.

**ARTICLE 3
COVENANTS**

3.1 Product Returns.

3.1.1 On and after the Effective Date, Seller shall process any returns of units of Product that were sold in the Territory with a Seller NDC number that are made to Seller, irrespective of whether Seller or any of its Affiliates or Buyer or any of its Affiliates sold such returned unit of Product. All other returns of units of Product following the Effective Date will be processed by Buyer. Returns will be processed in accordance with the processing Party's then-current returned goods policy, regardless of which Party made the corresponding original sale. A copy of each of Seller's and Buyer's returned goods policy as of the Effective Date is attached hereto as Schedule 3.1.1.

3.1.2 Buyer shall be financially responsible for return reimbursement for all units of Product sold on or after the Effective Date in the Territory. Seller shall be financially responsible for return reimbursement for units of Product sold prior to the Effective Date in the Territory. Notwithstanding the foregoing, Buyer and Seller shall be financially responsible for returns of units of Product included in Transition Lots on a proportional basis, based on the number of units of Product in such Transition Lot sold by or on behalf of Buyer (including by Seller under Section 2.10) after the Effective Date (which shall be Buyer's financial responsibility) and on the number of units of Product in such Transition Lot sold by Seller prior to the Effective Date (which shall be Seller's financial responsibility). Seller shall reimburse Buyer for all refunds paid by Buyer for returns of units of Product sold by Seller in the Territory prior to the Effective Date and Seller's proportionate share of refunds for returns of units of Product included in Transition Lots. Buyer shall reimburse Seller for all refunds paid by Seller for (x) returns of units of Product sold by or on behalf of Buyer in the Territory on or after the Effective Date and (y) Buyer's proportionate share of refunds for returns of units of Product included in Transition Lots. Buyer's reimbursement obligations to Seller under this Section 3.1.2 will be settled through the Net Margin Amount calculation during the period in which the Net Margin Amount is payable hereunder and, following such period, by direct payment within 30 days following Buyer's receipt of written invoice and supporting documentation from Seller. Seller's reimbursement obligations to Buyer under this Section 3.1.2 will be settled by direct payment within 30 days following Seller's receipt of written invoice and supporting documentation from Buyer.

3.1.3 Each Party shall promptly destroy, or cause to be promptly destroyed, all units of Product returned to it or its Affiliates that are required by applicable Law to be destroyed, in each case in a manner consistent with all applicable Law. Seller shall reimburse Buyer for Buyer's reasonable out-of-pocket costs for destruction of returned units of Product that were sold prior to the Effective Date, and Buyer shall reimburse Seller for Seller's reasonable out-of-pocket costs for destruction of all other returned units of Product.

3.1.4 Neither Buyer nor Seller shall instruct, recommend or attempt to induce Customers who have previously purchased a Product in the Territory to (a) return such Product when that would not otherwise have been the case but for such Party's instructions, recommendations or inducement or (b) delay the return of such Product.

3.2 Government Rebates and Price Reporting.

3.2.1 Allocation of Financial Responsibility.

(a) Seller shall be financially responsible for all Rebates with respect to the Products pursuant to Rebate claims under any government rebate programs (including all Rebates pursuant to Seller's Government Contracts and under any Medicaid Rebate Program) (collectively, "**Government Rebates**") for any portion of an invoice covering utilization in the [***] (as reflected in the covered period stated on such invoice).

(b) For Government Rebates for any portion of an invoice covering utilization in the [***] (as reflected in the covered period stated on such invoice) (i) Seller shall be financially responsible for the amount of such Government Rebates that is equal to the product of (x) a fraction, the numerator of which is the number of days in such Calendar Quarter included during the Rebate Tail Period and the denominator of which is the number of days in such Calendar Quarter, and (y) the amount of the Government Rebate and (ii) Buyer shall be financially responsible for the amount of such Government Rebates that is equal to the product of (A) one minus the fraction determined pursuant to clause (i) above and (B) the amount of Government Rebate.

(c) Buyer shall be financially responsible for all Government Rebates for any portion of an invoice covering utilization following the [***] (as reflected in the covered period stated on such invoice).

(d) The financial obligations of the Parties with respect to Government Rebates and Medicare Part D Coverage Gap Discounts with respect to the Products shall be determined solely by reference to the date of dispensing of units of Product, as reflected in the applicable invoice for such Government Rebates and Medicare Part D Coverage Gap Discounts, and Seller shall not have any obligation to request from any Governmental Authority or other Third Party documentation supporting the utilization reflected on such invoices.

3.2.2 Seller shall be administratively responsible for processing all such Government Rebates for Product labeled with an NDC number of Seller, including payment of invoices, and shall conduct the process for disputing Rebate claims as if Seller were at all times itself financially responsible for the Rebate liability; *provided, however*, that Buyer shall be administratively responsible for processing Tricare Rebates for units of Product labeled with an NDC number of Seller beginning on the date that such Product is added to Buyer's FSS contract. Buyer shall be administratively responsible for processing all such Government Rebates for Product labeled with an NDC number of Buyer. Buyer will provide to Seller, on a quarterly basis within 15 days after Seller's request therefor, information in Buyer's possession or control relating to Product labeled with an NDC number of Seller sold by or on behalf of Buyer that Seller reasonably needs in order to comply with applicable Laws relating to Government Rebates, in each case, in the format of, and containing the information customarily used by Buyer with respect to its own Government Rebate processing. To the extent Seller reasonably requires additional data or a different format, the Parties agree to negotiate in good faith in an effort to address Seller's concerns. If Seller does not timely process payments for the Government Rebates for which Seller is administratively responsible under this Section 3.2.2, then, other than in the event such failure to timely process payments is due to Buyer's failure to provide timely information in Buyer's possession or control to Seller in accordance with this Section 3.2.2, Seller shall be responsible for, and shall timely pay, any fees, penalties, or assessments of any kind relating to late or untimely payments.

3.2.3 To the extent that Seller processes any Government Rebates that are the financial responsibility of Buyer, and subject to requirements and obligations of the Seller under this Section 3.2, Buyer shall reimburse Seller therefor, which reimbursement will be settled through the Net Margin Amount calculation during the period in which the Net Margin Amount is payable hereunder and, following such period, by direct payment within 30 days after receipt of invoices that describe the requested payments in reasonable summary level detail and include reasonable supporting documentation. To the extent that Buyer processes any Government Rebates that are the financial responsibility of Seller, Seller shall reimburse Buyer therefor, which reimbursement will be settled by direct payment within 30 days after receipt of invoices that describe the requested payments in reasonable summary level detail and include reasonable supporting documentation.

3.2.4 [***].

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3.2.11 [***].

3.2.12 [***].

3.2.13 [***].

3.2.14 [***].

3.3 Commercial Rebates.

3.3.1 [***].

3.3.2 [***].

3.3.3 [***].

3.3.4 [***].

3.4 Chargeback Claims.

3.4.1 [***].

3.4.2 [***].

3.4.3 [***].

3.5 Branded Prescription Drug Fees.

3.5.1 [***].

3.5.2 [***].

3.5.3 [***].

3.5.4 [***].

3.6 PDUFA Fees. [***].

3.7 Reconciliation. [***].

3.8 Impact of Price Increases on Payment Claims. [***].

3.9 Government Contracts.

3.9.1 [***].

3.9.2 [***].

3.10 Distribution Services Fees. [***]

3.11 Customer Notification; Order Transition. [***].

3.12 Price Appreciation Credits. [***].

**ARTICLE 4
COMPENSATION**

4.1 Services Fees. In consideration for the performance of the Services by Seller, and the performance by Seller of its other obligations hereunder, Buyer shall pay Seller the applicable amounts set forth on Schedule 2.1(a) and Schedule 4.1 per Calendar Quarter for each Calendar Quarter during the Transition Period (the “**Services Fee**”) and the aggregate Supply Price for Finished Product supplied under Section 2.10.3(b) or Section 2.10.4 during each Calendar Quarter during the Transition Period; *provided*, [***]. To the extent that Seller ceases providing Services during (but not at the end of) a Calendar Quarter, Buyer shall be responsible for paying a prorated quarterly Services Fee for such partial Calendar Quarter. In addition, Buyer shall reimburse Seller (upon receipt of applicable receipts and other reasonable supporting documentation) for any Out-of-Pocket Costs.

4.2 Invoicing. Seller shall, on a Calendar Quarterly basis, invoice Buyer for the Services Fee for the preceding Calendar Quarter [(***)], the aggregate Supply Price for the preceding Calendar Quarter and all Out-of-Pocket Costs incurred by Seller in the preceding Calendar Quarter (collectively, “**Invoiced Amounts**”).

4.3 Due Date. Invoiced Amounts will be paid through the Net Margin Amount during the period hereunder in which the Net Margin Amount is payable. Thereafter, Buyer shall pay (a) the Services Fee due for each Calendar Quarter on or prior to the fifth Business Day of the immediately following Calendar Quarter and (b) each invoice for Supply Prices and Out-of-Pocket Costs due under this Agreement promptly, but in no event later than 30 days, after the date of receipt of such invoice and supporting documentation (such as Third Party invoices). All payments to be made under this Agreement shall be made in United States dollars and paid by wire transfer of immediately available funds (i) to such account designated by Buyer by written notice to Seller from time to time with respect to payments to be made to Buyer hereunder or (ii) to such account designated by Seller by written notice to Buyer from time to time with respect to payments to be made to Seller hereunder. Any payments under this Agreement that are not made on or before the applicable due date shall bear interest a rate equal to the lesser of (x) [(***)] percent per annum above the Prime Rate, as reported in the print edition of *The Wall Street Journal*, Eastern Edition, on the date such payment was due or, if unavailable, on the latest date prior to the payment due date on which such rate is available, and (y) the maximum rate permitted under applicable Law, calculated on a daily basis, based on the actual number of days elapsed from the payment due date to the date of actual payment.

4.4 Taxes.

4.4.1 The amounts payable by Buyer to Seller pursuant to this Agreement (“**Payments**”) shall not be reduced on account of any Taxes unless required by applicable Law. Seller alone shall be responsible for paying any and all Taxes (other than withholding Taxes required to be paid by Buyer) levied on account of, or measured in whole or in part by reference to, any Payments it receives. Buyer shall deduct or withhold from the Payments any Taxes that it is required by applicable Law to deduct or withhold. If Seller is entitled under any applicable Tax treaty to a reduction of rate of, or the elimination of, or recovery of, applicable withholding Tax, it shall deliver to Buyer or the appropriate Governmental Authority (with the assistance of Buyer to the extent that this is reasonably required and is expressly requested by Seller in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve Buyer of its obligation to withhold Tax, and Buyer shall apply the reduced rate of withholding, or dispense with the withholding, as the case may be, to the extent it complies with the applicable Tax treaty. If, in accordance with the foregoing, Buyer withholds any amount, it shall make timely payment to the proper Taxing Authority of the withheld amount, and send to Seller proof of such payment within 60 days following that payment.

4.4.2 All Payments are stated exclusive of Indirect Taxes. If any Indirect Taxes are chargeable in respect of any Payments, Buyer shall pay such Indirect Taxes at the applicable rate in respect of any such Payments following the receipt, where applicable, of an Indirect Taxes invoice in the appropriate form issued by Seller in respect of such Payments, such Indirect Taxes to be payable on the due date of the payment of the Payments to which such Indirect Taxes relate. Seller shall issue its invoices for all amounts payable under this Agreement consistent with Indirect Tax requirements and irrespective of whether the sums may be netted for settlement purposes.

4.5 Records; Audit.

4.5.1 Each Party shall keep and maintain, and shall cause its Affiliates to keep and maintain, complete and accurate records and books of account documenting all expenses and all other data necessary for the calculation of the amounts payable to the other Party under this Agreement consistent with its standard procedures and policies in the ordinary course of business for a period of three years after such expenses are incurred, unless a longer retention period is required by applicable Law.

4.5.2 Upon either Seller's or Buyer's request, the other such Party shall, and shall cause each of its Affiliates engaged in the performance of activities under this Agreement to, permit the requesting Party and its Representatives to engage, on a non-contingency basis, an Auditor to inspect and audit the records and books of account maintained by it pursuant to Section 4.5.1 in order to confirm the accuracy and completeness of such records and books of account and all payments hereunder; *provided*, that no Party shall be entitled to exercise its inspection and audit rights under this Section 4.5.2 more than once per calendar year, unless, in any case, any prior audit resulted in an adjustment to amounts due hereunder. The Party requesting the audit shall bear all out-of-pocket costs and expenses incurred in connection with any inspection or audit performed pursuant to this Section 4.5.2; *provided, however*, that the audited Party shall reimburse the Party requesting the audit for all reasonable costs and expenses incurred by such Party in connection with such inspection or audit if any such audit identifies an underpayment to the auditing Party or an overpayment to the audited Party hereunder in excess of 10% of the amounts actually payable. The full amount of any underpayment or overpayment as applicable shall be payable to the applicable Party plus accrued interest at a rate equal to the lesser of (i) two percent per annum above the Prime Rate, as reported in the print edition of *The Wall Street Journal*, Eastern Edition, on the date such payment was due or, if unavailable, on the latest date prior to the payment due date on which such rate is available, and (ii) the maximum rate permitted under applicable Law, calculated on a daily basis, based on the actual number of days elapsed from the payment due date to the date of actual payment. All information disclosed pursuant to this Section 4.5.2 shall be subject to the non-disclosure and non-use provisions set forth in Article 6.

4.6 Right to Discontinue Services Following Failure to Pay. Seller reserves the right to discontinue any Service under this Agreement in the event Buyer fails to remit payment of any undisputed portion of any invoiced amount and such failure to remit payment remains uncured for more than fifteen days after written notice by Seller.

ARTICLE 5
OWNERSHIP OF ASSETS: INTELLECTUAL PROPERTY AND RIGHTS OF REFERENCE

5.1 Ownership. This Agreement and the performance of the Services hereunder shall not affect the ownership of any Intellectual Property Rights or other assets. Subject to Section 5.2, no Party shall gain, by virtue of this Agreement or the Services hereunder, by implication or otherwise, any rights of ownership or use of any property or Intellectual Property Rights owned by any other Party. All rights, title and interest in and to all Intellectual Property Rights conceived or made by Seller, its Affiliates or its subcontractors in the course of Seller's performance of Services and other activities under this Agreement shall be solely owned by Seller. In addition, except as otherwise expressly set forth in this Agreement, under no circumstances shall Seller be obligated to deliver or provide to Buyer, or otherwise make available or provide Buyer access to, any item (including any data, Contract, report, diagram or other such information or writing) which Seller is not otherwise obligated to provide to Buyer under the terms of the Asset Purchase Agreement or any Ancillary Agreement.

5.2 Limited License. Solely for and with respect to performance of Services and other activities under this Agreement during the Transition Period, Buyer (on behalf of itself and its Affiliates) hereby grants to Seller and its Affiliates a limited, non-exclusive, royalty-free, non-transferable license and right of reference, with the right to grant further licenses and rights of reference, to all Purchased Intellectual Property, Purchased Regulatory Approvals, Purchased Product Records, and Purchased Regulatory Documentation included within the Purchased Assets, all Buyer Regulatory Approvals and Documentation and all intellectual property rights owned or controlled by Buyer or its Affiliates, in each case, that are necessary or useful to perform, and solely for purposes of performing, the Services or Seller's other obligations hereunder.

ARTICLE 6
CONFIDENTIALITY

Section 5.4 of the Asset Purchase Agreement is hereby incorporated by reference into this Agreement, *mutatis mutandis; provided*, that the Confidentiality Period shall be the period from the Effective Date through the [***] anniversary of the termination or expiration of this Agreement and the term Confidential Information shall include the terms and conditions of this Agreement.

ARTICLE 7
LIMITATION OF LIABILITY; INDEMNIFICATION

7.1 Limitation of Liability. NOTWITHSTANDING ANYTHING TO THE CONTRARY CONTAINED IN THIS AGREEMENT, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, NEITHER BUYER NOR SELLER SHALL BE LIABLE TO THE OTHER OR THEIR AFFILIATES OR ANY THIRD PARTY, FOR ANY CLAIMS, DEMANDS OR SUITS FOR CONSEQUENTIAL, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE, INDIRECT OR MULTIPLE DAMAGES, FOR LOSS OF PROFITS, REVENUE OR INCOME, DIMINUTION IN VALUE OR LOSS OF BUSINESS OPPORTUNITY (IN EACH CASE, WHETHER OR NOT FORESEEABLE AT THE EFFECTIVE DATE), FOR ANY DAMAGES CALCULATED BY REFERENCE TO A MULTIPLIER OF REVENUE, PROFITS, EBITDA OR SIMILAR METHODOLOGY, CONNECTED WITH OR RESULTING FROM ANY BREACH OF THIS AGREEMENT, OR ANY ACTIONS UNDERTAKEN IN CONNECTION WITH, OR RELATED HERETO, INCLUDING ANY SUCH DAMAGES WHICH ARE BASED UPON BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE AND MISREPRESENTATION), BREACH OF WARRANTY, STRICT LIABILITY, STATUTE, OPERATION OF LAW OR ANY OTHER THEORY OF RECOVERY. The maximum aggregate liability of Seller and its Affiliates to Buyer or any of its Affiliates with respect to this Agreement shall be \$[***] (the "**Seller Cap**"); *provided, however*, that the Seller Cap shall not apply to any failure of Seller to pay or reimburse any amounts owed to Buyer hereunder, including the Net Margin Amount payable to Buyer under Section 2.10.2 and amounts payable by Seller pursuant to Article 3, and shall not apply in the event of Seller's fraud, or willful misconduct, or otherwise if prohibited by applicable Law.

7.2 Indemnification. Except as set forth in the Asset Purchase Agreement with respect to matters covered thereby and subject to this Article 7, Buyer shall indemnify, defend and hold harmless the Seller Indemnitees from and against, and reimburse and compensate any of them for, any and all Losses incurred by any such Person in connection with any Third Party Claims to the extent caused by (a) the breach by Buyer or any of its Affiliates of this Agreement; (b) the gross negligence or willful misconduct of Buyer or any of its Affiliates in the performance of obligations under this Agreement; or (c) the performance by Seller, its Affiliates or its subcontractors of Seller's obligations under this Agreement, except, in each case, for Seller-Related Losses. Subject to this Article 7, Seller shall indemnify, defend and hold harmless the Buyer Indemnitees from and against, and reimburse and compensate any of them for, any Seller-Related Losses incurred by any of them; *provided*, that, the maximum aggregate liability of Seller and its Affiliates under this Section 7.2 for Seller-Related Losses (other than Seller Related Losses that are amounts payable by Seller pursuant to this Agreement and other than as set forth in the proviso in Section 7.1) shall not exceed the Seller Cap. All indemnification claims made pursuant to this Section 7.2 shall be governed by Section 7.2.2 of the Asset Purchase Agreement. This Agreement may only be enforced against, and any claim, action, suit or other legal proceeding based upon, arising out of, or related to this Agreement, or the negotiation, execution or performance of this Agreement, may only be brought against the entities that are expressly named as Parties and then only with respect to the specific obligations set forth herein with respect to such Party. No past, present or future director, officer, employee, incorporator, manager, member, partner, stockholder, Affiliate, agent, attorney or other Representative of a Party or of any Affiliate of a Party, or any of their successors or permitted assigns, shall have any liability for any obligations or liabilities of a Party under this Agreement or for any claim, action, suit or other legal proceeding based on, in respect of or by reason of the transactions contemplated hereby.

ARTICLE 8 TERM AND TERMINATION

8.1 Term. This Agreement shall commence on the Effective Date and shall continue in full force and effect until [•] (the "**Initial Transition Period**"), unless earlier terminated in accordance with this Article 8; *provided* that (a) for the Post-Marketing Study Services, the term during which such services will be provided will commence on the Effective Date and end on the date on which Seller delivers the last final study report described in Schedule 2.1(a), (b) for any particular Transitional Service, the term during which such Transitional Service will be provided will commence on the Effective Date and end on [***], and (c) for the Manufacturing Services, the term during which such services will be provided will commence on the Effective Date and end on the later of (i) the date that is the last day of the Initial Transition Period and (ii) the date on which the Manufacturing Services are terminated pursuant to Section 8.2.5 (the applicable period in this Section 8.1, the "**Transition Period**").

8.2 Termination of Services.

8.2.1 Upon the mutual written consent of Buyer and Seller, the Parties may, at any time prior to the end of the Transition Period, terminate this Agreement in its entirety or with respect to all or any Services, whereupon, from and after the date of termination specified in such written consent, Seller's obligation to provide such Services to Buyer and its Affiliates shall cease; *provided*, that if termination of any Service materially inhibits or prevents Seller's ability to provide any other Services (as determined in Seller's reasonable discretion), such other Services shall be deemed terminated.

8.2.2 In the event that either Seller, on the one hand, or Buyer, on the other hand (the "**Breaching Party**") breaches any of its material obligations under this Agreement, Seller (if Buyer is the Breaching Party) or Buyer (if Seller is the Breaching Party) may terminate this Agreement upon 30 days' prior written notice (such 30-day period, the "**Notice Period**") to the Breaching Party, specifying the breach and its claim of right to terminate; *provided*, that the termination of this Agreement shall not become effective at the end of the Notice Period if (a) the Breaching Party cures such breach during the Notice Period or (b) such breach cannot be cured during the Notice Period and the Breaching Party commences and diligently pursues actions to cure such breach within the Notice Period, in which case the Breaching Party shall have an additional 30-day period to cure such breach before such termination shall become effective, *provided, further*, that a fifteen day cure period shall apply to any breach of a payment obligation hereunder and such cure period shall not be subject to extension in accordance with the preceding proviso.

8.2.3 Each of Buyer and Seller may terminate this Agreement immediately upon written notice to the other such Party if such other Party or any direct or indirect parent company of the other Party suffers an Insolvency Event.

8.2.4 Each of Buyer and Seller may terminate this Agreement to the extent provided in Section 9.1.

8.2.5 [***]

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

8.4 Surviving Obligations. Without limiting the foregoing, Article 1, Section 2.10.2, Section 2.10.3, Section 2.13, Article 3, Article 4, Article 5, Article 6, Article 7, Section 8.2, Section 8.3, this Section 8.4 and Article 9 shall survive the termination or expiration of this Agreement for any reason.

ARTICLE 9 MISCELLANEOUS

9.1 Force Majeure. Except for the obligation to pay monies due and owing, neither Party shall be liable for any failure to perform or any delays in performance, and no such Party shall be deemed to be in breach or default of its obligations set forth in this Agreement, if, to the extent and for so long as, such failure or delay is due to any causes that are beyond its reasonable control and without its fault or negligence, including, without limitation, such causes as acts of God, natural disasters, fire, flood, severe storm, earthquake, civil disturbance, lockout, riot, order of any court or administrative body, embargo, acts of government, war (whether or not declared), acts of terrorism, epidemics, pandemics (including COVID-19) or other similar causes (“**Force Majeure Event**”). In the event of a Force Majeure Event, Seller or Buyer, if prevented from or delayed in performing, shall promptly give notice to the other such Party and shall use commercially reasonable efforts to avoid or minimize the delay. In the event that the delay continues for a period of at least 30 days, the other such Party may elect to (a) suspend performance and extend the time for performance for the duration of the Force Majeure Event, or (b) terminate this Agreement without any liability to any Party.

9.2 Independent Contractor. The Parties and each of their respective Affiliates shall each be an independent contractor in the performance of its obligations hereunder. No Third Party, including any employee of any Party or any of such Party’s Affiliates, shall have or acquire any rights by reason of this Agreement.

9.3 Assignment. Neither this Agreement nor any of the rights or obligations of the Parties hereunder may be assigned by Buyer, on the one hand, or Seller, on the other hand, without the prior written consent of Seller (in the case of Buyer) or Buyer (in the case of Seller), as applicable; *provided, however*, that (i) either Party may assign or delegate any or all of its rights or obligations hereunder to an Affiliate (but no such assignment shall relieve the assigning Party of any of its obligations under this Agreement), and Seller may delegate any or all of its obligations hereunder to subcontractors, in each case, without the prior written consent of the other Party and (ii) following the termination or expiration of all Services other than the Manufacturing Services and the Post-Marketing Study Services, Buyer may transfer this Agreement to a direct or indirect purchaser of the Products and the Product Business without the prior written consent of Seller (but no such assignment shall relieve Buyer of any of its obligations under this Agreement). Subject to the first sentence of this Section 9.3, this Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns. Any attempted assignment or transfer in violation of this Section 9.3 shall be null and void. Notwithstanding the foregoing, in the event a Party assigns its rights or obligations under this Agreement or otherwise makes payments from a jurisdiction other than the jurisdiction in which such party is organized (each an “**Assignment**”), and immediately after such Assignment the amount of Tax required to be withheld on any payment pursuant to this Agreement is greater than the amount of such Tax that would have been required to have been withheld absent such Assignment, then such increased withholding Tax shall be borne by the Party making such Assignment.

9.4 **No Benefit to Third Parties.** Except for the rights of any indemnified Person under Article 7, this Agreement is for the sole benefit of the Parties and their respective successors and permitted assigns and nothing herein expressed or implied shall give or be construed to give to any Person, other than the Parties and such successors and assigns, any legal or equitable rights hereunder.

9.5 **Notices.**

9.5.1 Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement (each, a “**Notice**”) shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if delivered by hand or sent by facsimile transmission or by email of a PDF (or similar electronic) attachment (with transmission confirmed) or by overnight registered mail, courier or express delivery service that maintains records of delivery, addressed to the applicable Party at its address specified below. Such Notice shall be deemed to have been received: (a) as of the date delivered by hand or by overnight registered mail, courier or express delivery service; or (b) on the day sent by facsimile or email; *provided* that the sender has received confirmation of transmission (by facsimile or email receipt confirmation or confirmation by telephone or, with respect to facsimile only, email) prior to 6:00 p.m. Eastern Time on such day (and if confirmation is received after 6:00 p.m. Eastern Time, such Notice shall be deemed to have been delivered on the following Business Day).

(i) If to Seller, to:

Eisai Inc.
200 Metro Boulevard
Nutley, NJ 07110
Attention: General Counsel

with a copy (which shall not constitute notice) to:

Covington & Burling LLP
One CityCenter
850 Tenth Street, NW
Washington, D.C. 20001
Attention: Michael J. Riella
E-mail: mriella@cov.com

(ii) If to Buyer, to:

Catalyst Pharmaceuticals, Inc.
355 Alhambra Circle, Suite 801
Coral Gables, FL 33134
Attention: General Counsel

with a copy (which shall not constitute notice) to:

Akerman LLP
201 East Las Olas Blvd., 18th Floor
Fort Lauderdale, FL 33301
Attention: Phillip B. Schwartz, Esq.

9.6 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future Law, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to Buyer and Seller.

9.7 Governing Law. This Agreement, the negotiation, execution or performance of this Agreement and any Disputes that may be based upon, arise out of or relate hereto (whether for breach of contract, tortious conduct or otherwise), will be governed by, and enforced and construed in accordance with, the Law of the State of Delaware, including its statutes of limitations, without regard to the conflict of Laws rules of such state that would result in the application of the Laws of another jurisdiction.

9.8 Jurisdiction. The Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of the courts of the Delaware Court of Chancery and the United States District Court for the District of Delaware sitting in New Castle County for any Dispute, action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement, and agree not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such courts. EACH PARTY HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT TO ANY LITIGATION DIRECTLY OR INDIRECTLY ARISING OUT OF, UNDER OR IN CONNECTION WITH THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR DISPUTES RELATING HERETO. EACH PARTY (a) CERTIFIES THAT NO REPRESENTATIVE OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER AND (b) ACKNOWLEDGES THAT IT AND THE OTHER PARTY HAVE BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 9.8.

9.9 Service of Process. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 9.5 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such court.

9.10 Amendments and Waivers. This Agreement may not be modified, amended, altered or supplemented except upon the execution and delivery of a written agreement executed by both Parties. No course of dealing between the Parties shall be effective to amend or waive any provision of this Agreement. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by any Party of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.

9.11 Joint Drafting. The Parties have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the Parties and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any of the provisions of this Agreement.

9.12 Counterparts. This Agreement may be executed in any number of counterparts and manually or electronically, and each such counterpart hereof shall be deemed to be an original instrument, but all such counterparts together shall constitute but one agreement. Delivery of an executed counterpart of a signature page of this Agreement by facsimile or other electronic transmission shall be effective as delivery of a manually executed original counterpart of this Agreement.

9.13 Entire Agreement. This Agreement, together with the Asset Purchase Agreement (including the Schedules and Exhibits expressly contemplated thereby and attached thereto), the Schedules expressly contemplated hereby and attached hereto, the Disclosure Schedules, the Ancillary Agreements, the Confidentiality Agreement and the other agreements, certificates and documents delivered in connection herewith or therewith or otherwise in connection with the transactions contemplated hereby and thereby, contain the entire agreement between the Parties with respect to the transactions contemplated hereby or thereby and supersede all prior agreements, understandings, promises and representations, whether written or oral, between the Parties with respect to the subject matter hereof and thereof.

[Signature page follows]

IN WITNESS WHEREOF, Seller and Buyer have duly executed this Agreement as of the date first written above.

EISAI INC.

By: _____
Name:
Title:

CATALYST PHARMACEUTICALS, INC.

By: _____
Name:
Title:

[Signature Page to Transition Services Agreement]

Schedule 1.1

[**]

Schedule 1.1 - 1

Schedule 2.1(a)

[**]

[**]

Schedule 2.1(a) - 1

Schedule 2.1(b)

Transitional Services

[***]

Schedule 2.1(b) - 1

Schedule 2.10.2(b)

Form of Quarterly Statement

[***]

Schedule 2.10.2(b) - 1

Schedule 2.10.3(c)

[**]

[**]

Schedule 2.10.32.10.3(c) - 1

Schedule 2.10.4

Supply Prices

[***]

Schedule 2.10.4 - 1

Schedule 2.12.2

[**]

[**]

Schedule 2.12.2 - 1

Schedule 3.1.1

Returned Goods Policies

[***]

Schedule 3.1.1 - 1

Schedule 3.2.7

Medicaid and PHS 340B Program Price Reporting

[***]

Schedule 3.2.7 - 1

Schedule Supplement 3.2.7

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Schedule 3.2.8

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[**]

Schedule 3.2.8 - 1

Schedule 3.3.1

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[**]

Schedule 3.3.1 - 1

Schedule 4.1

Services Fees

[***]

Schedule 4.1 - 1

*Certain identified information has been excluded from this exhibit because it is both (i) not material, and (ii) would likely cause competitive harm to the registrant if publicly disclosed. [***] indicates that information has been redacted.*

Exhibit H

Form of Supply Agreement

SUPPLY AGREEMENT

between

EISAI CO., LTD.

and

CATALYST PHARMACEUTICALS, INC.

Dated as of [•], 2022

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SUPPLY AGREEMENT

This Supply Agreement (this “**Agreement**”) is made and entered into effective as of [•], 2022 (the “**Effective Date**”) by and between Eisai Co., Ltd., a corporation organized under the laws of Japan (“**Seller**”), and Catalyst Pharmaceuticals, Inc., a corporation organized under the laws of Delaware (“**Buyer**”). Seller and Buyer are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**.”

RECITALS

WHEREAS, Seller and Buyer are parties to an Asset Purchase Agreement, dated as of [•], 2022 (the “**Asset Purchase Agreement**”), pursuant to which Buyer is purchasing from Seller and its Affiliates certain assets related to the Product (as defined in the Asset Purchase Agreement) in the Buyer Territory;

WHEREAS, Buyer desires to engage Seller to Manufacture the Supplied Product for Buyer on the terms and conditions set forth herein; and

WHEREAS, Seller wishes to Manufacture the Supplied Product for Buyer on the terms and conditions set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the mutual benefits to be derived from this Agreement and of the representations, warranties, conditions, agreements and promises contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, hereby agree as follows:

ARTICLE 1 DEFINITIONS

1.1 Certain Defined Terms. Unless otherwise specifically provided herein, the following terms shall have the meaning set forth in this Section 1.1. Capitalized terms not otherwise defined herein shall have the meanings ascribed thereto in the Asset Purchase Agreement.

“**Agreement**” has the meaning set forth in the preamble hereto.

“**API**” means the active pharmaceutical ingredient perampanel.

“**Bulk Product**” means the Product in unfinished tablet form.

“**Buyer Corporate Names**” means the corporate names and other Trademarks and logos identified on Schedule 1 and such other corporate names or other Trademarks and logos that Buyer uses to identify itself or any of its Affiliates as Buyer may designate to Seller in writing from time to time.

“**Buyer Intellectual Property**” means (a) any data, information and know-how that (i) is not generally known, (ii) is Controlled by Buyer or its Affiliates as of the Effective Date or during the Term, and (iii) is necessary or useful for Seller to Manufacture the Supplied Product hereunder; and (b) all Trademarks Controlled by Buyer used in the Manufacture or Exploitation of the Product, including the Buyer Corporate Names.

“**Buyer Territory**” means the United States and its territories and possessions.

“**Calendar Quarter**” means each successive period of three calendar months commencing on January 1, April 1, July 1 or October 1, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date, and the last Calendar Quarter shall end on the last day of the Term.

“**cGMP**” means all applicable current Good Manufacturing Practices, including as specified in (a) the ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients Q7, and (b) 21 CFR § 210-211, 600 and 610.

“**Contract Year**” means the 12 month period during the Term commencing on January 1 and ending on December 31 of each calendar year; *provided, however* that the first Contract Year shall be the period beginning on the Effective Date and ending on December 31st in the calendar year in which the Effective Date occurs and the last Contract Year shall be the period beginning on January 1 and ending on the effective date of expiration or termination of this Agreement.

“**Discretionary Manufacturing Changes**” means changes to the process of Manufacturing of Supplied Product other than Required Manufacturing Changes.

“**FTE**” means the equivalent of the work of one employee of Seller or any of its Affiliates full time for one Calendar Year (consisting of at least a total of 1,920 hours per Calendar Year of work directly related to this Agreement). If any employee of Seller or any of its Affiliates who devotes fewer than 1,920 hours per year in providing work directly related to this Agreement, such employee shall be treated as an FTE on a pro-rata basis, calculated by dividing the actual number of hours worked by such employee in providing such work by 1,920. Any such employee who devotes more than 1,920 hours per year in providing work directly related to this Agreement shall be treated as one (1) FTE.

“**FTE Costs**” means [***]

“**FTE Rate**” means [***]

“**Materials**” means all API, excipients, components, labeling and packaging materials and other materials required to Manufacture the Supplied Product.

“**Minimum Order Quantity**” means Seller’s minimum quantity for any Purchase Order for the API or any SKU of Supplied Product, set forth on Schedule 2. Seller shall obtain Buyer’s prior written consent, not to be unreasonably withheld, conditioned or delayed, prior to changing the Minimum Order Quantity for any SKU of the Supplied Product.

“**Non-Conformity Exceptions**” means, with respect to the Supplied Product, any non-conformity to the extent directly caused by the incorporation into the Manufacturing process for the Supplied Product of any [***].

“**PPI**” means the Producer Price Index for Finished Goods, Pharmaceutical Preparations, as it appears in the periodical PPI Detailed Report as published by the Bureau of Labor Statistics of the United States Department of Labor and using the latest version of data published as of the date of adjustment.

“**Product**” means the pharmaceutical products commercialized in the Territory as of the Closing Date by Seller or its Affiliates as FYCOMPA® and described in NDA #202834.

“**Product Purchase Price**” means, with respect to the API or the applicable SKU of the Supplied Product, the purchase price payable hereunder for such API or such SKU as set forth on Schedule 2 for 2022, as adjusted from time to time in accordance with this Agreement.

“**Purchase Order**” means a written purchase order in a form reasonably acceptable to Seller that sets forth, with respect to the period covered thereby, (a) the quantity (which shall be the applicable Minimum Order Quantity or whole multiples thereof) of the API and the quantity and SKUs of Supplied Product to be delivered by Seller to Buyer and (b) the required delivery dates therefor.

“**Qualification Batch**” means a batch of a Bulk Product SKU or API (as applicable) that meets the Specifications and that is in compliance with applicable Laws that is Manufactured to assess the ability of a party to Manufacture such batch in accordance with the then-current Manufacturing process.

“**Seller Territory**” means the entire world other than the Buyer Territory.

“**Services**” means the Manufacture and supply of the Supplied Products pursuant to this Agreement.

“**SKU**” means stock keeping unit.

“**Specifications**” means the written specifications (including applicable labeling specifications) as set forth in the Quality Agreement, as such specifications may be amended or supplemented in accordance with Section 2.9 and the Quality Agreement.

“**Supplied Product**” means (a) the API and (b) those certain SKUs of Bulk Product specified on Schedule 2.

The terms set forth below shall have the meanings ascribed thereto in the referenced section:

<u>Term</u>	<u>Section</u>
Agreement	Preamble
Asset Purchase Agreement	Preamble
Assignment	10.2
Breaching Party	9.2.2
Buyer	Preamble
Buyer Indemnitees	8.2
Discretionary Manufacturing Changes	2.9.3
Dispute	10.4
Effective Date	Preamble
Firm Forecast	2.2
Forecast	2.2
Notice	10.6.1
Notice Period	9.2.2
Party(ies)	Preamble
Required Manufacturing Changes	2.9.2
Seller	Preamble
Seller Indemnitees	8.1
Term	9.1
Testing Laboratory	2.8.2
Third Party Claims	8.1

1.2 Construction. Except where the context otherwise requires, wherever used, the singular includes the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word “or” is used in the inclusive sense (and/or). The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The terms “including” and “include” and variations thereof shall not be deemed to be terms of limitation, but rather shall be deemed to be followed by the words “without limitation.” The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against any Party. Unless otherwise specified or where the context otherwise requires, (a) references in this Agreement to any Article, Section or Schedule are references to such Article or Section of or Schedule to this Agreement; (b) references in any Section to any clause are references to such clause of such Section; (c) “hereof,” “hereto,” “hereby,” “herein” and “hereunder” and words of similar import when used in this Agreement refer to this Agreement as a whole and not to any particular provision of this Agreement; (d) references to a Person are also to its permitted successors and assigns; (e) references to a Law include any amendment or modification to such Law and any rules or regulations issued thereunder, in each case, as in effect at the relevant time of reference thereto; (f) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently amended, replaced or supplemented from time to time, as so amended, replaced or supplemented and in effect at the relevant time of reference thereto; (g) “extent” in the phrase “to the extent” means the degree to which a subject or other thing extends, and such phrase does not mean simply “if” and (h) references to monetary amounts are denominated in U.S. dollars.

ARTICLE 2
MANUFACTURE, PURCHASE AND SALE OF PRODUCT

2.1 Supply. Subject to the terms and conditions of this Agreement, during the Term, Seller shall Manufacture and supply to Buyer, and Buyer agrees to purchase from Seller, Supplied Product for sale or distribution by Buyer solely in the Buyer Territory in accordance with the terms and conditions of the Asset Purchase Agreement.

2.2 Forecasts.

2.2.1 On the Effective Date, Buyer shall provide Seller with a written good faith forecast in the form attached hereto as Schedule 3 estimating Buyer's monthly requirements for the API and each SKU of Supplied Product (in multiples of Seller's Minimum Order Quantities) during the then-current calendar month and each of the succeeding 24 calendar months thereafter. Thereafter, not later than 30 days prior to the commencement of each subsequent calendar month during the Term, Buyer shall provide Seller with a rolling 24-calendar month forecast for the Supplied Product that covers the succeeding 24-calendar month period (or the period until the expiration of the Term, as applicable, if shorter), with the forecast for all 24 months to be provided on a monthly basis and further broken down by SKU of Supplied Product (including relevant NDC) and number of kilograms of API and number of units of each SKU of Supplied Product (each such 24-calendar month forecast, a "**Forecast**"). Each Forecast (and ultimate Purchase Order) shall not exceed the upper or lower quantities by more than the following: [***]. The first [***] calendar months of each Forecast shall be a "**Firm Forecast**" and shall represent a binding commitment of Buyer to purchase the quantities of API and SKUs of Supplied Product included therein. Otherwise, except as set forth in this Section 2.2.1, a Forecast shall not be binding on either Party; provided, however, that Buyer will notify Seller as soon as practicable in the event that Buyer reasonably believes that the forecasted quantities for any Supplied Product for any month in the non-binding period will need to be adjusted to exceed by more than [***]% the quantities listed for such Supplied Product for such month set forth in the most recent Forecast and the Parties will engage in good-faith discussions regarding how to address such adjustments.

2.2.2 In addition to the forecasts described in Section 2.2.1, Buyer shall also provide to Seller, on the Effective Date, a non-binding three-year good faith forecast for its requirements of API and each SKU of Supplied Product on a quarterly basis. Subsequently throughout the Term, Buyer shall supply Seller by January 1st of each year, a non-binding three-year good faith forecast for its requirements for API and each SKU of Supplied Product by unit on a quarterly basis.

2.3 Purchase Orders.

2.3.1 On or prior to the first Business Day of each month, Buyer shall submit to Seller Purchase Orders by SKU corresponding to the Product volumes shown for the last month of the Firm Forecast of the then-current Forecast. Such Purchase Orders shall be submitted [***].

2.3.2 The quantity of API and each SKU of Supplied Product specified in any Purchase Order for delivery in any Calendar Quarter shall not be less than or more than the quantities of the API or such SKU of the Supplied Product set forth in the Firm Forecast applicable for the calendar months comprising such Calendar Quarter (other than, as applicable, the initial and supplemental Purchase Orders contemplated under Section 2.3.1).

2.3.3 Except with respect to the initial Purchase Order, Buyer hereby acknowledges and agrees that the lead time on all Purchase Orders is at least [***] days. Each Purchase Order shall set out the date upon which Buyer requests that the relevant Supplied Product shall be delivered.

2.3.4 Subject to the terms hereof, Seller shall accept each submitted Purchase Order that complies with this Section 2.3 and Seller shall be obligated to Manufacture and deliver the quantities of Supplied Product in accordance with the delivery schedule set forth in each accepted Purchase Order; *provided*, that if Seller timely delivers at least 90% of the quantity of each Supplied Product set forth in a Purchase Order within five Business Days of the required delivery date set forth therein, Seller shall be deemed to have fully performed its obligations with respect to such Purchase Order; *provided, further*, that Seller shall not be required to deliver Supplied Product more than once in any Calendar Quarter. In the event that the quantity of Supplied Product delivered by Seller differs from the quantity requested in the applicable Purchase Order, Buyer shall pay Seller for the quantity of Supplied Product actually delivered rather than the quantity requested in the Purchase Order.

2.4 Failure or Inability to Supply Supplied Product.

2.4.1 Seller shall promptly notify Buyer in writing if at any time Seller has reason to believe that Seller will not be able to (a) fill a Purchase Order for Supplied Product in accordance with the delivery schedule specified therein by Buyer and pursuant to the terms and conditions of this Agreement and the Quality Agreement or (b) supply Supplied Product to Buyer in satisfaction of the most recent Firm Forecast which notice in either case shall provide Buyer with information on the extent of the expected shortfall of supply and the reasons for such shortfall. Upon such notice of a supply problem, or in any event upon Seller's failure to satisfy, within the delivery time frame specified by Buyer in a Purchase Order, a portion of the Supplied Product ordered by Buyer in compliance with this Agreement and the Quality Agreement:

(a) Buyer and Seller shall promptly meet and work together, in good faith, to identify an appropriate resolution to the supply problem and to prevent future supply problems. Any agreed resolution to the supply problem shall be set forth in a writing executed by both Parties; and

(b) without limiting Buyer's other remedies hereunder, Seller shall deliver the Supplied Product that is subject to such shortfall as soon as is reasonably practicable following the required delivery date, on a date to be agreed with the Buyer, in accordance with Section 2.8.

2.4.2 Notwithstanding anything to the contrary herein, except in respect of gross negligence or willful misconduct, the remedies set forth in this Section 2.4 and in Section 2.5 shall be Buyer's sole and exclusive remedy with respect to any failure of Seller to supply Supplied Product in accordance with this Agreement.

2.4.3 If Seller is unable to Manufacture and deliver quantities of Supplied Product as required hereunder then, without prejudice to Buyer's other rights and remedies hereunder, Seller shall treat Buyer equitably as compared to the other recipients of product Manufactured and supplied by Seller and its Affiliates that rely on the same Materials or impacted Manufacturing site. Such equitable treatment shall include: (a) allocating in a fair and reasonable manner available Materials or capacity at the affected Manufacturing site between (i) the Products, (ii) products Manufactured for commercialization by the Seller or its Affiliates that rely on the same Materials or impacted Manufacturing site and (iii) products Manufactured for commercialization by Third Parties that rely on the same Materials or impacted Manufacturing site, such that Buyer receives its pro rata share based on the ratio of the Parties' respective forecasted demand and (b) not deprioritizing Buyer based on the revenue generated by Seller or its Affiliates by supplying Supplied Product to Buyer when compared to supplying Supplied Product to Seller, its Affiliates, or Third Parties.

2.5 Late Delivery Compensation. If Seller fails to deliver conforming Supplied Product before [***], then Buyer shall be entitled to compensation, as a non-exclusive remedy [***]. The compensation due pursuant to this Section 2.5 shall be applied as a credit against amounts due to Seller pursuant to future invoices.

2.6 Changes in Purchase Orders. Purchase Orders may be amended only by mutual agreement of the Parties.

2.7 Delivery. Seller shall deliver or arrange for delivery of Supplied Product purchased by Buyer to a carrier designated by Buyer in the applicable Purchase Order hereunder (*provided* that such designated carrier shall be subject to approval by Seller, such approval not to be unreasonably withheld, conditioned or delayed), EXW (Incoterms 2020), Seller's (or, as the case may be, its Affiliate's or designated Third Party's) Manufacturing plant or warehouse. For the sake of clarity, (a) delivery shall occur at Seller's (or, as the case may be, its Affiliate's or designated Third Party's) Manufacturing plant or warehouse, and (b) all shipping costs (including any and all related insurance costs and import taxes, duties and tariffs) associated with the delivery of Supplied Product hereunder (whether shipped from Seller's or, as the case may be, its Affiliate's or designated Third Party's Manufacturing plant or warehouse) shall be paid by Buyer. Risk in and title to the Product purchased under this Agreement shall pass upon delivery to Buyer's carrier. Each delivery of Supplied Product shall be accompanied by a certificate of analysis as provided in Section 4.1 and such other documents as shall be required by the Quality Agreement.

2.8 Rejected Goods/Shortages.

2.8.1 Notice; Replacement. Buyer shall notify Seller in writing of (a) any claim that any Supplied Product, as of the time of delivery thereof, fails to conform to the applicable Specifications (including any Non-Conformity Exception) and/or which has not been Manufactured in accordance with applicable Law, cGMP and the Quality Agreement, or (b) any shortage in quantity of any shipment of the Supplied Product, in each case as soon as reasonably practicable, but not later than 30 days following delivery of such Supplied Product in the case of patent defects (i.e. a non-conformance that was reasonably detectable through Buyer's inspection in accordance with the Quality Agreement) and, in the case of latent defects, not later than 10 days from Buyer's discovery of a latent defect that was not reasonably detectable through Buyer's inspection in accordance with the Quality Agreement. If the Parties agree that the Supplied Product fails to conform (other than for any Non-Conformity Exception) or that there is a shortage, then Seller, at Buyer's option, shall replace the nonconforming Supplied Product or make up the shortage at the next practicable delivery date.

2.8.2 Disputes.

(a) If Seller disagrees with Buyer's claim that any Supplied Product fails to meet the applicable Specifications as of the time of delivery and/or has not been Manufactured in accordance with applicable Law, cGMP and the Quality Agreement, Seller shall notify Buyer within 14 days and representatives of Seller and Buyer shall attempt to resolve such dispute in good faith. If the representatives cannot resolve such dispute within 30 days, a sample of the applicable Supplied Product shall be submitted by Seller and Buyer to an independent testing laboratory or other appropriate expert mutually acceptable to the Parties (the "**Testing Laboratory**") for evaluation against the applicable Specifications and the requirements of applicable Law, cGMP and the Quality Agreement and the test results obtained by the Testing Laboratory shall be final and controlling, absent fraud or manifest error. The fees and expenses of the Testing Laboratory shall be borne by Buyer if the Testing Laboratory confirms that the applicable Supplied Product conforms and otherwise by Seller. In the event the test results indicate that the Supplied Product in question does not conform (other than for any Non-Conformity Exception), then Seller shall replace the nonconforming Product at the next practicable delivery date.

2.8.3 Costs and Expenses; Disposal. Seller shall bear the costs and expenses of making up any shortage of Supplied Product and replacing any such nonconforming Supplied Product. Buyer shall make arrangements with Seller for the return or disposal of any nonconforming Supplied Product, and the reasonable and documented costs of such return or disposal shall be paid by Buyer.

2.8.4 Exclusive Remedy. Notwithstanding anything to the contrary herein but subject to Section 5.1, except in respect of gross negligence or willful misconduct, the provisions of this Section 2.8 shall be the sole and exclusive remedy available to Buyer with respect to nonconforming Supplied Product.

2.9 Manufacturing Changes.

2.9.1 Change to Specifications Generally. In the event of a proposed change by either Party in the Specifications during the Term with respect to the Supplied Product, the proposing Party shall promptly notify the other Party of the proposed change and shall provide the other Party with documentation in support of such proposed change. Within a period of 30 Business Days from receipt of such notice, the Parties shall initiate review and comment on such proposed change, including discussion of any improvements to any Intellectual Property that might be generated as a result. Seller and Buyer shall cooperate in good faith to design a plan to resolve any Supplied Product supply issues that may result from changes in the Specifications, and no change will be made without the written mutual agreement of both Parties (such agreement not to be unreasonably withheld, conditioned or delayed) except as required by applicable Law.

2.9.2 Required Manufacturing Changes. Each Party shall give the other Party reasonable written notice prior to any changes to the process of Manufacturing Supplied Product for sale in the Buyer Territory that are required by cGMP or other applicable Law (collectively, “**Required Manufacturing Changes**”). The Party required by cGMP or other applicable Law to make Required Manufacturing Changes shall use commercially reasonable efforts to carry out such Required Manufacturing Changes and the other Party shall, where required, reasonably assist in carrying out such changes.

2.9.3 Discretionary Manufacturing Changes.

(a) If, as part of a general change program at its Manufacturing site(s) which will not disadvantage the Supplied Products as compared with other products Manufactured or supplied by Seller or its relevant Affiliate(s) at such site(s), Seller desires to make a Discretionary Manufacturing Change, Seller shall notify Buyer, providing reasonable details and the Parties shall promptly meet and discuss in good faith the reasonable concerns of Buyer relating thereto, with Seller providing such information to Buyer as Buyer may reasonably request. Provided that Seller follows the foregoing process and uses reasonable efforts to make such accommodations as Buyer may reasonably request to minimize the impact of such Discretionary Manufacturing Changes on the Product Business, Seller may make reasonable Discretionary Manufacturing Changes at Seller’s sole cost and expense (for the avoidance of doubt including any cost or expense incurred by Buyer reasonably and directly as a result of any such Discretionary Manufacturing Change), but Seller shall not implement any change prior to receipt of approval, if required, of any such variations to any Regulatory Approvals for the Product in the Territory.

(b) Buyer may request Discretionary Manufacturing Changes and if Seller agrees (such agreement not to be unreasonably withheld, delayed, or conditioned) to make any such Discretionary Manufacturing Changes, Seller will provide the estimated cost and time of implementing any such Discretionary Manufacturing Changes to Buyer along with the terms on which Seller would be willing to make such Discretionary Manufacturing Changes. Upon Buyer’s written acceptance of such cost and time estimate, the Parties shall cooperate in making such Discretionary Manufacturing Changes and Seller shall use commercially reasonable efforts to implement such Discretionary Manufacturing Changes as requested by Buyer.

2.9.4 Regulatory Approvals. If a change is made to the Specifications or Manufacturing process for the Supplied Product, then prior to the implementation of such change Buyer shall (a) submit all supplemental applications or reports to Governmental Authorities with respect to the Product, if required, to reflect such change, (b) obtain all approvals required by Governmental Authorities (including required Regulatory Approvals) with respect to such change and (c) promptly provide copies of the materials referenced in clauses (a) and (b) to Seller. Seller shall reasonably cooperate with Buyer in connection therewith. Buyer shall reasonably cooperate with Seller (including by providing relevant data and other information), to allow Seller to comply with all of its regulatory obligations in connection with any such change.

2.9.5 Costs of Manufacturing Changes. All costs and expenses reasonably incurred by Seller (including FTE Costs, FDA filings, write offs and other costs due to such changes associated with obsolete raw materials, work-in-process and finished product inventories, and all printed materials, including packaging and labeling materials) associated with any changes to the Specifications or other Manufacturing changes (including Required Manufacturing Changes and Discretionary Manufacturing Changes) shall be borne by Buyer, and Buyer shall promptly reimburse Seller upon invoice therefor, except for costs and expenses associated with any Discretionary Manufacturing Change initiated by Seller, in which case such costs and expenses shall be borne solely by Seller.

2.9.6 Changes from One Manufacturing Facility to Another. [***]

2.10 Materials. Seller shall obtain all Materials required for the Manufacture of the Supplied Product at its sole cost and expense. The costs of the Materials and the management and procurement of such Materials shall be included in, and not be incremental to, the Product Purchase Price.

2.11 Subcontracting of Manufacture. During the Term Seller shall not be entitled to subcontract to a Third Party its obligations to Manufacture the Supplied Product except to the subcontractors specified in Schedule 5 for the activities specified therein. Any further subcontracting of Manufacturing activities shall be agreed between the Parties.

2.12 Limited License. Buyer, on behalf of itself and its Affiliates, hereby grants to Seller and its Affiliates a non-exclusive, royalty-free, fully paid-up, non-transferable (except as provided in Section 10.2) license under the Buyer Intellectual Property and a right of reference and use under the Buyer Regulatory Approvals and Documentation, with the right to grant further licenses and sublicenses or rights of reference and use, in each case, to the extent necessary for Seller and its Affiliates to perform their obligations hereunder.

2.13 Technology Transfer.

2.13.1 [***]

2.13.2 [***]

2.13.3 [***]

**ARTICLE 3
PRICING AND PAYMENT**

3.1 Pricing.

3.1.1 Initial Price. The initial Product Purchase Price for the API and each SKU of Supplied Product is set forth on Schedule 2.

3.1.2 Adjustments. On January 1, 2024 and each January 1 thereafter during the Term, the Product Purchase Price shall be subject to adjustment by Seller for inflation by a percentage less than or equal to the percentage increase in the PPI for the immediately preceding 12-month period. For the avoidance of doubt such adjusted Product Purchase Price shall not apply to any Supplied Product to be delivered under any Purchase Orders submitted prior to such increase.

3.2 Payment.

3.2.1 Purchase Price. Seller shall invoice Buyer for the then-applicable Product Purchase Price for all Supplied Product promptly following the delivery of such Supplied Product.

3.2.2 Terms. All undisputed payments due to Seller under this Agreement shall be (a) paid in full by Buyer without any deduction or set-off (except as otherwise set out in this Agreement), within [***] days from the date of any invoice delivered pursuant to this Agreement and (b) made by deposit of Dollars in the requisite amount to such bank account as Seller may from time to time designate by notice to Buyer. Any undisputed amounts under this Agreement that are not paid on or before the applicable due date shall bear interest at the rate of the lesser of [***]% per annum above “Prime”, as defined in the print edition of *The Wall Street Journal*, Eastern Edition, on the payment due date or, if unavailable, on the latest date prior to the payment due date on which such rate is available, and the maximum rate allowed by Law, calculated on a daily basis on the actual number of days elapsed from the payment due date to the date of actual payment. If Buyer disputes any portion of an invoice provided by Seller hereunder, it shall promptly pay the undisputed portion as provided in clause (a) above and shall provide Seller with written notice of the disputed portion and its reasons therefor, and Buyer shall not then be obligated to pay such disputed portion unless and until it is determined in accordance with Section 10.4 that such amount is owed by Buyer in which case such portion shall be paid within [***] days of such determination. The Parties shall use good faith efforts to resolve any such disputes promptly.

3.2.3 Default. With respect to payment defaults not cured within [***] days after receipt of written notice from Seller to Buyer, Seller shall, in its sole discretion, and without prejudice to any other of its accrued rights, be entitled to suspend the supply of the Supplied Product, which suspension shall not result in or constitute a breach of any of Seller’s obligations under this Agreement. For the avoidance of doubt, the failure to pay disputed portions of invoices pursuant to Section 3.2.2 shall not be a payment default until such dispute is finally resolved in Seller’s favor and the Buyer has failed to make such payment within [***] days of such determination.

3.2.4 Taxes. To the extent not otherwise exempted as set forth herein, Buyer shall pay all Taxes arising under or in connection with this Agreement, exclusive of Taxes based on Seller’s employees, benefits plans, income or net worth. Official receipts indicating proof of payment of any such taxes shall be secured and made available to Seller upon request as evidence of payment.

ARTICLE 4 QUALITY ASSURANCE, ACCESS AND REGULATORY MATTERS

4.1 Testing; Certificate of Analysis. Seller shall perform, or cause to be performed, the tests required to be performed by Seller pursuant to the Quality Agreement on each lot of Supplied Product delivered pursuant to this Agreement before delivery thereof to Buyer. Seller shall deliver a certificate of analysis and other documents required under the Quality Agreement with respect to each lot of Supplied Product concurrently with delivery thereof that sets forth the items tested, Specifications and test results, and that contains the other types of information that are set out in the Quality Agreement or as have otherwise been approved by mutual agreement of the Parties.

4.2 Records. Seller shall maintain or shall cause to be maintained all Manufacturing records, all records of shipment and all validation data relating to the Supplied Product to the extent, and for the time periods, required by applicable Laws with respect to the Supplied Product, in each case, in accordance with its customary procedures. Buyer shall bear all reasonable costs and expenses associated with translating any such records into the English language to the extent such records customarily are maintained by Seller or its Affiliates in a language other than English, if Buyer requests such translation.

4.3 Regulatory Compliance.

4.3.1 Seller shall (a) advise Buyer promptly if an authorized agent of the FDA (or other Governmental Authority) visits its Manufacturing facilities where the Supplied Product is being Manufactured or quality tested, and (b) furnish to Buyer all material information supplied by the FDA (or other Governmental Authority) in connection with such visit, including any Form 483 observations and responses and any establishment inspection reports within 15 days after its receipt of such information, in each case ((a) and (b)), to the extent that Seller determines in its reasonable discretion that the Supplied Product in the Buyer Territory would be materially and adversely affected by such information. To the extent possible, Seller shall provide to Buyer notice of the submission of any draft response to the FDA at least five Business Days prior to submission of the response to FDA and Seller shall reasonably consider any input from Buyer in such submission.

4.4 Access to Facilities. No more than once during any Contract Year (unless any such inspection reveals a material compliance issue, in which event Buyer shall have the right to conduct additional inspections to verify that such issue has been remediated), upon the reasonable prior written request of Buyer, Buyer shall have the right to inspect those portions of the facilities of Seller where the Supplied Product is being Manufactured, during regular business hours, to ascertain compliance with applicable Laws and the Specifications, subject to the reasonable rules and regulations of Seller, including any confidentiality and health and safety restrictions.

4.5 Quality Agreement. Each Party shall perform its obligations under the Quality Agreement. To the extent any provision of the Quality Agreement conflicts with any provision of this Agreement with respect to any matter regarding the quality of the Supplied Product, the provisions of the Quality Agreement shall govern. Otherwise, the provisions of this Agreement shall govern.

**ARTICLE 5
PRODUCT RECALLS**

5.1 Product Recalls.

5.1.1 Subject to Section 5.1.2, and except as provided in Section 5.9.2 of the Asset Purchase Agreement with respect to the period between the Effective Date and the transfer of the Purchased Regulatory Approvals to Buyer or its designee, any recalls or market withdrawals of the Product in the Buyer Territory shall be implemented by or under the direction of Buyer (*provided*, that Buyer shall inform Seller and, to the extent reasonably possible, consult with Seller prior to initiating any recall or market withdrawal of the Product in the Buyer Territory) and Seller shall cooperate with Buyer as reasonably requested in effecting any such recall or market withdrawal of the Product in the Buyer Territory. Buyer shall be responsible for all costs of each recall or market withdrawal, including costs incurred by Seller, except to the extent such recall or market withdrawal results from Seller's gross negligence, willful misconduct or breach of this Agreement.

5.1.2 Buyer shall not unreasonably object to a bona fide recall or market withdrawal reasonably requested in writing by Seller relating to Supplied Product. In the event Buyer unreasonably elects not to initiate a recall or market withdrawal of the Product as requested by Seller under this Section 5.1.2, any reasonable and documented costs and expenses related to Buyer's failure to perform such recall or market withdrawal shall be borne by Buyer.

5.2 Disputes. If there is any dispute concerning which Party's acts or omissions gave rise to any recall or market withdrawal of the Product, such dispute shall be referred for decision to an independent expert, acting as an expert and not as an arbitrator, to be appointed by agreement between Buyer and Seller. The decision of such independent expert shall be in writing and, except for fraud or manifest error, shall be binding on both Buyer and Seller. The costs of such independent expert shall be borne by the Party who is found to be responsible for the recall or market withdrawal by the independent expert. After such determination, costs shall be paid by the responsible Party in accordance with Section 5.1.

**ARTICLE 6
REPRESENTATIONS AND WARRANTIES**

6.1 Warranties and Covenants of Seller.

6.1.1 Seller Warranties and Covenants. Seller hereby warrants and covenants to Buyer that:

(a) all Supplied Product delivered pursuant to the terms hereof by Seller (or any subcontractor thereof) to Buyer during the Term will, at the time of such delivery be in accordance with the Specifications, has been and shall have been Manufactured in accordance with all applicable Laws, cGMP and the Quality Agreement, and shall not be adulterated or misbranded within the meaning of the Act;

(b) it has or shall obtain and maintain all permits and licenses required by any Governmental Authority for the provision of the Services; and

(c) it will not employ, contract with, or retain any person directly or indirectly to perform any Services if such person is presently debarred by any Governmental Authority from working in or providing services to any pharmaceutical or biotechnology company under any applicable Law, or otherwise disqualified or suspended from performing services such as the Services. If during the Term, the Seller or any person employed or retained by it to perform the Services is debarred, disqualified or suspended by any Governmental Authority, Seller shall immediately notify Buyer of the same.

6.1.2 Exclusion of Other Warranties. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY WARRANTY HEREUNDER WHETHER EXPRESS OR IMPLIED BY STATUTE, CUSTOM OF THE TRADE OR OTHERWISE AND ANY SUCH WARRANTY IS HEREBY EXCLUDED (INCLUDING, IN THE CASE OF SELLER, IN RESPECT OF THE SUPPLIED PRODUCT SUPPLIED HEREUNDER, ANY WARRANTY RELATING TO THE DESCRIPTION OR QUALITY OF THE SUPPLIED PRODUCT, ITS MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR USE UNDER ANY CONDITIONS, NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF ANY PERSON OR AS TO ANY OTHER MATTER).

6.2 Covenants of Buyer. Buyer hereby covenants to Seller that: (a) any changes to the Specifications for the Supplied Product requested by Buyer will comply with the Regulatory Approvals for such Supplied Product and all applicable Laws; (b) Buyer has obtained, or will obtain, all applicable licenses, registrations and permits necessary to take delivery of, market, sell, import, export, distribute and otherwise dispose of the Supplied Product.

ARTICLE 7 CONFIDENTIALITY

7.1 Confidentiality Obligations. Section 5.4 of the Asset Purchase Agreement is hereby incorporated by reference into this Agreement, *mutatis mutandis; provided*, that the “Confidentiality Period” shall be the period from the Effective Date through the [***] anniversary of the termination or expiration of this Agreement or, if longer, with respect to any Confidential Information that constitutes a trade secret under applicable Law, until such time as such Confidential Information no longer constitutes a trade secret under applicable Law and the term “Confidential Information” shall include the terms and conditions of this Agreement.

ARTICLE 8 LIMITATION OF LIABILITY, INDEMNIFICATION AND INSURANCE

8.1 Indemnification of Seller. Subject to the provisions of this Article 8, Buyer shall indemnify, defend and hold harmless Seller and its Affiliates, and their respective officers, directors and employees (collectively, “**Seller Indemnitees**”), from and against, and compensate and reimburse the Seller Indemnitees for, any and all Losses actually incurred by any Seller Indemnitee in connection with any and all suits, investigations, claims or demands of Third Parties (collectively, “**Third Party Claims**”) arising from or occurring as a result of: (a) any breach by Buyer or its Affiliates of this Agreement or the Quality Agreement or the gross negligence or willful misconduct of Buyer or its Affiliates in the performance of its obligations hereunder or under the Quality Agreement, (b) Buyer’s failure to perform a recall or market withdrawal of the Supplied Product requested by Seller under Section 5.1.2 or (c) any claim by a Third Party that the Manufacture or supply of the Supplied Product in accordance with the terms of this Agreement infringes, misappropriates or otherwise violates the Intellectual Property Rights of such Third Party solely to the extent such infringement, misappropriation or violation is as a direct result of any change in the Specifications or Manufacturing process for the Supplied Product requested by Buyer during the Term, in each case ((a) through (c)), except to the extent of those Losses for which Seller has an obligation to indemnify Buyer or any Buyer Indemnitee pursuant to Section 8.2, as to which Losses each Party shall indemnify the other Party and the Seller Indemnitees or the Buyer Indemnitees, as applicable, to the extent of their respective liability for such Losses.

8.2 Indemnification of Buyer. Subject to the provisions of Section 6.1.2 and this Article 8, Seller shall indemnify, defend and hold harmless Buyer and its Affiliates, and their respective officers, directors and employees (collectively, “**Buyer Indemnitees**”), from and against, and compensate and reimburse the Buyer Indemnitees for, any and all Losses incurred by any Buyer Indemnitee in connection with any and all Third Party Claims arising from or occurring as a result of any breach by Seller or its Affiliates of this Agreement or the Quality Agreement or the gross negligence or willful misconduct of Seller or its Affiliates or any of Seller’s subcontractors in the performance of its obligations hereunder or under the Quality Agreement; except to the extent of those Losses for which Buyer has an obligation to indemnify Seller or any Seller Indemnitee pursuant to Section 8.1, as to which Losses each Party shall indemnify the other Party and the Seller Indemnitees or the Buyer Indemnitees, as applicable, to the extent of its liability for such Losses. Notwithstanding the foregoing, Seller shall have no obligation under this Section 8.2 to indemnify or hold harmless Buyer or any Buyer Indemnitee with respect to Third Party Claims arising from or occurring as a result of Buyer’s failure to perform a recall or market withdrawal of the Supplied Product requested by Seller under Section 5.1.2.

8.3 Indemnification Procedures. All indemnification claims in respect of Buyer or any Buyer Indemnitee shall be made solely by Buyer and all indemnification claims in respect of Seller or any Seller Indemnitee shall be made solely by Seller and, in each case, shall be governed by Section 7.2 of the Asset Purchase Agreement. Notwithstanding anything herein to the contrary, the Parties’ respective indemnification obligations under this Article 8 shall not apply to any Losses for which such Party is entitled to indemnification under the Asset Purchase Agreement (without giving effect to the limitations in Section 7.3 of the Asset Purchase Agreement).

8.4 Limitation on Damages and Liability.

8.4.1 TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, EXCEPT IN CIRCUMSTANCES OF (I) FRAUD OR FRAUDULENT MISREPRESENTATION, (II) GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, OR (III) BREACH OF THE PROVISIONS OF ARTICLE 7, AND WITHOUT LIMITING THE PARTIES’ OBLIGATIONS UNDER SECTION 8.1 OR 8.2 WITH RESPECT TO THIRD PARTY CLAIMS, NEITHER BUYER NOR SELLER SHALL BE LIABLE TO THE OTHER, OR THEIR AFFILIATES, FOR ANY CLAIMS, DEMANDS OR SUITS FOR CONSEQUENTIAL, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE, INDIRECT OR MULTIPLE DAMAGES, INCLUDING LOSS OF PROFITS, REVENUE OR INCOME, DIMINUTION IN VALUE OR LOSS OF BUSINESS OPPORTUNITY (WHETHER OR NOT FORESEEABLE AT THE EFFECTIVE DATE) CONNECTED WITH OR RESULTING FROM ANY BREACH OF THIS AGREEMENT, OR ANY ACTIONS UNDERTAKEN IN CONNECTION HEREWITH, OR RELATED HERETO (OR THE ASSET PURCHASE AGREEMENT OR ANY OTHER ANCILLARY AGREEMENT TO THE EXTENT SUCH LIABILITY ARISES AS A RESULT OF A PARTY’S ACTIVITIES UNDER THIS AGREEMENT), INCLUDING ANY SUCH DAMAGES THAT ARE BASED UPON BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE AND MISREPRESENTATION), BREACH OF WARRANTY, STRICT LIABILITY, STATUTE, OPERATION OF LAW OR ANY OTHER THEORY OF RECOVERY.

8.4.2 TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, EXCEPT IN CIRCUMSTANCES OF (I) FRAUD OR FRAUDULENT MISREPRESENTATION, (II) GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, OR (III) BREACH OF THE PROVISIONS OF ARTICLE 7, SELLER SHALL NOT BE LIABLE FOR LOSSES HEREUNDER (OR UNDER THE ASSET PURCHASE AGREEMENT OR ANY OTHER ANCILLARY AGREEMENT TO THE EXTENT SUCH LIABILITY ARISES AS A RESULT OF SELLER'S ACTIVITIES UNDER THIS AGREEMENT) IN AN AGGREGATE AMOUNT GREATER THAN [***].

ARTICLE 9
TERM AND TERMINATION

9.1 Term. Unless earlier terminated in accordance with Section 9.2, the term of this Agreement shall commence on the Effective Date and shall continue in force, unless terminated in accordance with this Article 9, for an initial term of seven years (the “**Initial Term**”) and thereafter shall automatically renew for additional periods of [***] months (each an “**Extension Term**” and the Initial Terms together with any Extension Terms the “**Term**”) unless (a) Buyer gives Seller no less than [***] months written notice prior to the end of the Initial Term or any Extension Term of Buyer’s intention to not extend the Term, (b) following Tech Transfer Completion, Seller gives Buyer no less than [***] months’ written notice prior to the end of the Initial Term or any Extension Term of Buyer’s intention to not extend the Term; or (c) this Agreement is terminated in accordance with this Article 9.

9.2 Early Termination. This Agreement may be terminated prior to the expiration of the Term as follows:

9.2.1 Mutual Agreement. This Agreement may be terminated upon the mutual written agreement of Buyer and Seller at any time.

9.2.2 Termination for Material Breach. In the event that either Party (the “**Breaching Party**”) breaches any of its material obligations under this Agreement, the other Party may terminate this Agreement upon [***] days’ prior written notice (such [***]-day period, the “**Notice Period**”) to the Breaching Party, specifying the breach and its claim of right to terminate; *provided*, that the termination of this Agreement shall not become effective at the end of the Notice Period if the Breaching Party cures such breach during the Notice Period.

9.2.3 Termination for Insolvency. Either Party may terminate this Agreement immediately upon written notice to the other Party if the other Party or any direct or indirect parent company of the other Party: (a) files in any court or with any other Governmental Authority pursuant to any Law of a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of that Person or of its assets; (b) proposes a written agreement for the composition or extension of its debts; (c) is served with an involuntary petition against it, filed in any insolvency or bankruptcy proceeding, and such petition is not dismissed within 60 days after the filing thereof; (d) consents to the appointment or taking possession by a receiver, liquidator, assignee, custodian, trustee, sequestrator (or similar official) of such Person or for any substantial part of its property or the making of any assignment for the benefit of creditors or (e) has issued or levied against its property any judgment, writ, warrant of attachment or execution or similar process against a substantial portion of such Person’s property.

9.2.4 Termination Following Withdrawal. Either Party may terminate this Agreement upon [***] days’ prior written notice to the other Party, in the event that Governmental Authorities cause the withdrawal of the Product from every jurisdiction in the Buyer Territory.

9.2.5 Termination for Force Majeure. Either Party may terminate this Agreement to the extent permitted pursuant to Section 10.1.

9.2.6 Termination for Convenience. Buyer may terminate this Agreement at any time during the Term upon at least [***] months’ prior written notice to the Seller. Seller may terminate this Agreement [***].

9.3 Consequences of Termination.

9.3.1 Upon the termination of this Agreement by Seller pursuant to Section 9.2.2 or 9.2.3: (a) all unfilled Purchase Orders shall be cancelled and (b) Buyer promptly shall pay to Seller (i) all undisputed amounts outstanding and remaining to be paid for Supplied Product delivered prior to the expiration or termination; (ii) the fair market value of Seller's then existing inventory of Materials and work in process, including useable API (as to which the Product Purchase Price for the API shall apply), that cannot otherwise be used in the business of Seller or its Affiliates without additional cost; and (iii) the applicable Product Purchase Price for all Supplied Product Manufactured, but not then delivered, by Seller in accordance with Buyer's then current Forecast.

9.3.2 Upon termination, other than by Seller pursuant to Section 9.2.2 or 9.2.3, or expiry of this Agreement: (a) all Supplied Product which has been Manufactured in accordance with the terms of this Agreement but not yet delivered shall be delivered by the Seller to the Buyer (and the Buyer shall pay for such Supplied Product in accordance with the terms of this Agreement); (b) all work-in-progress started by the Seller shall, at Buyer's election (i) completed by the Seller and delivered to the Buyer (and the Buyer shall pay for such Supplied Product in accordance with the terms of this Agreement), or (ii) destroy such work-in-progress at Buyer's cost (and Buyer shall pay for the costs reasonably incurred by Seller in Manufacturing such work-in-progress including all Materials consumed in the course of such Manufacture); and (c) after completion of any work-in-progress in accordance with (b) above, Seller shall make available any remaining Materials held by or on behalf of the Seller for Buyer to purchase at fair market value and collect from the relevant facility.

9.4 Accrued Rights; Surviving Obligations.

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

9.4.2 Survival. Without limiting the foregoing, Sections 2.12, 3.2, 4.2, 6.1.2, 9.3, and 9.4 and Article 5, 7, 8 and 10 of this Agreement shall survive the termination or expiration of this Agreement for any reason.

ARTICLE 10 MISCELLANEOUS

10.1 Force Majeure. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement (other than an obligation to make payments) to the extent such failure or delay is caused by or results from events beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, hurricanes, embargoes, shortages (to the extent outside of the control of the non-performing Party), epidemics or pandemics (including SARS-CoV-2 or COVID-19, and any evolutions or variants thereof or related or associated epidemics, pandemic or disease outbreaks, in each case only to the extent new lockdowns or other material restrictions are introduced by a Governmental Authority during the Term), quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts or other labor disturbances (whether involving the workforce of the non-performing Party or of any other Person, but only to the extent outside of the control of the non-performing Party), acts of God or acts, omissions or delays in acting by any Governmental Authority. The non-performing Party shall notify the other Party of such force majeure within 15 days after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform. Should the force majeure event last in excess of six consecutive months, the non-performing Party shall be entitled to terminate this Agreement.

10.2 Assignment. Neither this Agreement nor either Party's rights or obligations hereunder may be assigned or delegated by such Party without the prior written consent of the other Party, not to be unreasonably conditioned, withheld or delayed, and any attempted assignment or delegation of this Agreement or any of such rights or obligations by either Party without the prior written consent of the other Party shall be void and of no effect; *provided, however*, that (a) either Party may assign or delegate any or all of its rights or obligations hereunder to an Affiliate without the prior written consent of the other Party and (b) following termination or expiration of all Services other than the Post-Marketing Study Services and the Manufacturing Services under (and as defined in) the Transition Services Agreement, Buyer may assign or delegate any of its rights or obligations hereunder on the sale, transfer, or other disposition of all or substantially all of its rights to the Product Business; *provided further*, that such assigning Party shall remain liable to fulfill its obligations hereunder from and after such assignment. Subject to the preceding sentence, this Agreement will be binding upon, inure to the benefit of, and be enforceable by, the Parties and their respective successors and permitted assigns. Notwithstanding the foregoing, in the event a Party assigns its rights or obligations under this Agreement or otherwise makes payments from a jurisdiction other than the jurisdiction in which such Party is organized (each an "**Assignment**"), and immediately after such Assignment the amount of Tax required to be withheld on any payment pursuant to this Agreement is greater than the amount of such Tax that would have been required to have been withheld absent such Assignment, then such increased withholding Tax shall be borne by the Party making such Assignment.

10.3 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future Law, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties.

10.4 Dispute Resolution. Except for disputes arising under Section 2.8.2 or Section 5.2, if a dispute arises between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith (a “**Dispute**”), it shall be resolved pursuant to this Section 10.4.

10.4.1 General. Either Party shall have the right to refer any Dispute to the President, Eisai Demand Chain Systems of Seller and the President and Chief Executive Officer of Buyer who shall confer on the resolution of the issue. Any final decision mutually agreed to by such officers shall be conclusive and binding on the Parties. If such officers are not able to agree on the resolution of any such issue within 20 Business Days after such Dispute is first referred to them, either Party may, by written notice to the other Party, elect to initiate litigation in accordance with Section 10.5 for purposes of having the matter settled.

10.4.2 Interim Relief and Tolling. Notwithstanding anything herein to the contrary, (a) any relevant time period related to a matter that is the subject of a Dispute shall be tolled during any dispute resolution proceeding under this Section 10.4 and (b) nothing in this Section 10.4 shall preclude either Party from seeking interim or provisional relief, including a temporary restraining order, preliminary injunction or other interim equitable relief concerning a Dispute, if necessary to protect the interests of such Party. This Section 10.4.2 shall be specifically enforceable.

10.5 Governing Law, Jurisdiction, Venue and Service.

10.5.1 Governing Law. This Agreement, and all Disputes that may be based upon, arise out of or relate to this Agreement, or the negotiation, execution or performance of this Agreement (including any Dispute 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), will be governed by, and enforced and construed in accordance with, the Law of the State of Delaware, including its statutes of limitations, without regard to the conflict of Laws rules of such state that would result in the application of the Laws of another jurisdiction. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.

10.5.2 Jurisdiction. Subject to Section 10.9, the Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of the Delaware Chancery Court and the United States District Court for the District of Delaware sitting in New Castle County for any Dispute, action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement, and agree not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such courts. EACH PARTY HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT TO ANY LITIGATION DIRECTLY OR INDIRECTLY ARISING OUT OF, UNDER OR IN CONNECTION WITH THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR DISPUTES RELATING HERETO. EACH PARTY (a) CERTIFIES THAT NO REPRESENTATIVE OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER AND (b) ACKNOWLEDGES THAT IT AND THE OTHER PARTY HAVE BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 10.5.

10.5.3 Venue. The Parties further hereby irrevocably and unconditionally waive any objection to the laying of venue of any Dispute, action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement in the Delaware Court of Chancery and the United States District Court for the District of Delaware sitting in New Castle County, and hereby further irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.

10.5.4 Service. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 10.6.2 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such court.

10.6 Notices.

10.6.1 Notice Requirements. Except as otherwise provided in Section 2.3.1, any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement (each, a “**Notice**”) shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if delivered by hand or sent by facsimile transmission or email of a PDF (or similar electronic) attachment (with such transmission confirmed) or by overnight registered mail, courier or express delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in Section 10.6.2 or to such other address as the Party to whom notice is to be given may have provided to the other Party at least 10 days prior to such address taking effect in accordance with this Section 10.6. Such Notice shall be deemed to have been received: (a) as of the date delivered by hand or by overnight registered mail, courier or express delivery service; or (b) on the day sent by facsimile or email provided that the sender has received confirmation of transmission (by facsimile or email receipt confirmation or confirmation by telephone (with respect to facsimile only) or email) prior to 6:00 p.m. Eastern Time on such day (and if confirmation is received after 6:00 p.m. Eastern Time, such Notice shall be deemed to have been delivered on the following Business Day).

10.6.2 Address for Notice.

If to Seller, to:

Eisai Co., Ltd.
Bunkyo-ku, Tokyo 112-8088 Japan
Email: [***]

Attention: General Counsel

with a copy (which shall not constitute notice) to:

Eisai Inc. 200 Metro Boulevard
Nutley, NJ 07110
Attention: General Counsel

with a copy (which shall not constitute notice) to:

Covington & Burling LLP
One CityCenter 850 10th Street, NW
Washington, DC 20001
Email: mriella@cov.com
Attention: Michael Riella

If to Buyer, to:

Catalyst Pharmaceuticals, Inc.
355 Alhambra Circle, Suite 801
Coral Gables, FL 33134
Attention: Chief Legal and Compliance Officer

with a copy (which shall not constitute notice) to:

Akerman LLP
201 East Las Olas Blvd., 18th Floor
Fort Lauderdale, FL 33301
Attention: Philip B. Schwartz, Esq.

Cooley (UK) LLP 22 Bishopsgate
London EC2N 4BQ
United Kingdom
Attention: Michal Berkner
Frances Stocks Allen
Email: mberkner@cooley.com
fstocksallen@cooley.com

10.7 Amendment. This Agreement may not be modified, amended, altered or supplemented except upon the execution and delivery of a written agreement executed by both Parties; *provided*, that Seller shall be entitled to update Schedule 2 to reflect the Product Purchase Price in accordance with the definition of such term.

10.8 English Language. This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

10.9 Equitable Relief. The Parties agree that irreparable damage would occur in the event that any of the provisions of Article 7 were not performed in accordance with their specific terms or were otherwise breached. It is accordingly agreed that either Party shall be entitled to an injunction or injunctions, specific performance or other equitable relief to prevent breaches or threatened breaches of Article 7 and to enforce specifically the terms and provisions of Article 7 in any court of competent jurisdiction without proof of damages or otherwise, this being in addition to any other remedy to which it is entitled under this Agreement, at law or in equity, and the right of specific enforcement is an integral part of the transactions contemplated by this Agreement and without that right, no Party would have entered into this Agreement. Each Party hereby waives (a) any requirement that the other Party post a bond or other security as a condition for obtaining any such relief, and (b) any defenses in any action for specific performance, including the defense that a remedy at law would be adequate.

10.10 Waiver and Non-Exclusion of Remedies. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by any Party of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.

10.11 No Benefit to Third Parties. The covenants and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and, except for the rights of Buyer Indemnitees and Seller Indemnitees under Article 8, they shall not be construed as conferring any rights on any other Persons.

10.12 Expenses. Except as otherwise specified herein or in the Asset Purchase Agreement or in any other Ancillary Agreement, each Party shall bear any costs and expenses with respect to the Transactions.

10.13 Further Assurance. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

10.14 Relationship of the Parties. It is expressly agreed that Seller, on the one hand, and Buyer, on the other hand, shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither Seller, on the one hand, nor Buyer, on the other hand, shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

10.15 Counterparts. This Agreement may be executed in any number of counterparts and manually or electronically, and each such counterpart hereof shall be deemed to be an original instrument, but all such counterparts together shall constitute but one agreement. Delivery of an executed counterpart of a signature page of this Agreement by electronic transmission shall be effective as delivery of a manually executed original counterpart of this Agreement.

10.16 Entire Agreement. This Agreement, together with the Schedules expressly contemplated hereby and attached hereto, the Asset Purchase Agreement, the Ancillary Agreements, the Confidentiality Agreement and the other agreements, certificates and documents delivered in connection herewith or therewith or otherwise in connection with the Transactions, contain the entire agreement between the Parties with respect to the Transactions and supersede all prior agreements, understandings, promises and representations, whether written or oral, between the Parties with respect to the subject matter hereof and thereof.

[Signature page follows]

IN WITNESS WHEREOF, the Parties have each caused this Agreement to be duly executed as of the Effective Date.

EISAI CO., LTD.

By: _____
Name:
Title:

CATALYST PHARMACEUTICALS, INC.

By: _____
Name:
Title:

Schedule 1

Buyer Corporate Names

Catalyst Pharmaceuticals, Inc. – a Delaware corporation formerly known, until 2015, as Catalyst Pharmaceutical Partners, Inc.

Schedule 2

Supplied Product, SKUs, Product Purchase Prices and Minimum Order Quantities

[***]

Schedule 3

Forecast Template

[***]

Schedule 4

Initial Purchase Order

[***]

Schedule 5

Permitted Subcontractors

[***]

Schedule 6

Tech Transfer Plan Requirements

[***]

Catalyst Pharmaceuticals to Acquire U.S. Commercial Rights to FYCOMPA® (Perampanel) CIII From Eisai Co., Ltd

*Acquisition Expands The Company's Commercial Portfolio With An Established U.S. Marketed Product
Company Remains Dedicated To Growth Within Neurology Through Continued Active Business Development Strategy Into Synergistic Adjacencies
Transaction Includes Exclusive Period To Evaluate And Negotiate To Acquire A Rare Epilepsy Compound In Development
Acquisition Expected to be EBITDA and EPS Accretive in 2023*

CORAL GABLES, Fla., Dec. 19, 2022 (GLOBE NEWSWIRE) -- Catalyst Pharmaceuticals, Inc. ("Catalyst") (Nasdaq: CPRX), a commercial-stage biopharmaceutical company focused on in-licensing, developing, and commercializing novel medicines for patients living with rare diseases, today announced that it has entered into a definitive agreement with Eisai Co., Ltd, ("Eisai") under which Catalyst will acquire the U.S. rights for FYCOMPA® (perampanel) CIII and an exclusive option period to review, evaluate and negotiate to acquire a rare epilepsy asset currently in Eisai's pipeline. The acquisition adds a highly complementary and established marketed product in neurology that diversifies Catalyst's commercial product portfolio and paves the way for further expansion into other rare neurological diseases that address critical unmet medical needs.

Catalyst has been advised that Eisai's U.S. FYCOMPA net revenues for the 2022 fiscal year ending March 31, 2023, will approximate \$136 million. Catalyst expects the acquisition to be accretive upon closing to Catalyst's earnings in 2023 before interest, taxes, depreciation, and amortization ("EBITDA") and to EPS.

"This agreement broadens our commercial portfolio and provides an option to add a late-stage rare neurology asset that would further build upon our core competencies with differentiated medicines that treat rare neurological and epileptic disorders," said Patrick J. McEnany, Chairman and CEO of Catalyst. "Over the course of this year, our team has followed a focused and diligent process in pursuit of value-added transaction opportunities, and we are pleased to have delivered on this objective which we believe serves as a strategic catalyst for sustained future growth to our current strong revenues from FIRDAPSE®. Our portfolio expansion efforts and business development pipeline of prospects both continue to remain robust, with several additional opportunities under active due diligence that offer the potential to further implement our near and long-term growth strategy. We look forward to working closely with the Eisai FYCOMPA U.S. leadership to ensure a smooth and orderly transition of certain employees to the Catalyst team."

The acquisition of FYCOMPA® is expected to provide Catalyst with:

- A broader commercial product portfolio with the first and only non-competitive AMPA receptor antagonist approved for epilepsy.
- A growing revenue base and a synergistic asset, further adding to the company's already strong revenue growth of FIRDAPSE®.
- A successfully marketed product, expanding Catalyst's neurology footprint with the addition of a dedicated epilepsy sales force with a complementary call point.
- An exclusive option to evaluate and potentially add a rare epilepsy asset that would serve as a gateway to further expand the company's reach into rare neurological and epileptic disorders.
- The opportunity to build on the company's proven operational and commercial execution in neurology to further enhance the growth potential of FYCOMPA.

Catalyst believes that the acquisition of FYCOMPA will accelerate revenue growth and is expected to be accretive to EBITDA and EPS in 2023. After closing this transaction early in the first quarter of next year, we will be in a position to provide full revenue guidance for 2023.

FYCOMPA is expected to have patent protection through at least May 23, 2025, with possible patent protection into 2026.

Under the terms of the agreement, Eisai will receive an upfront payment of \$160 Million in association with this transaction and, in addition, may receive future milestone payments and royalties. Eisai has also granted Catalyst an exclusive option period to evaluate and negotiate the acquisition of a rare epilepsy compound in Eisai's pipeline.

The acquisition is structured as an all-cash purchase with no financing contingencies. The transaction is expected to be completed in the first quarter of 2023, subject to customary closing conditions and regulatory clearances in the United States and does not impact Catalyst's previously reported 2022 full-year FIRDAPSE revenue guidance. Catalyst and Eisai will work closely together to help ensure a seamless transition of certain key members of the FYCOMPA U.S. business unit to Catalyst, and to that end, the companies have negotiated a rigorous, short-term Transition Services Agreement and a longer-term Supply Agreement as part of the acquisition transaction.

About Catalyst Pharmaceuticals

Catalyst Pharmaceuticals is a commercial-stage biopharmaceutical company focused on in-licensing, developing, and commercializing novel medicines for patients living with rare diseases. With exceptional patient focus, Catalyst is committed to developing a robust pipeline of cutting-edge, best-in-class medicines for rare diseases. Catalyst's New Drug Application for FIRDAPSE® (amifampridine) Tablets 10 mg for the treatment of adults with Lambert-Eaton myasthenic syndrome ("LEMS") was approved in 2018 by the U.S. Food & Drug Administration ("FDA") and FIRDAPSE is commercially available in the United States as a treatment for adults and children ages six to seventeen with LEMS. Further, Canada's national healthcare regulatory agency, Health Canada, has approved the use of FIRDAPSE for the treatment of adult patients in Canada with LEMS.

For more information, visit the Company's website at www.catalystpharma.com.

About Eisai

Eisai's Corporate Concept is "to give first thought to patients and people in the daily living domain, and to increase the benefits that health care provides." Under this Concept [also known as our human health care (hhc) Concept], we aim to effectively achieve social good in the form of relieving anxiety over health and reducing health disparities. With a global network of R&D facilities, manufacturing sites and marketing subsidiaries, we strive to create and deliver innovative products to target diseases with high unmet medical needs, with a particular focus in our strategic areas of Neurology and Oncology.

In addition, **our continued commitment to the elimination of neglected tropical diseases (NTDs), which is a target (3.3) of the United Nations Sustainable Development Goals (SDGs)**, is demonstrated by our work on various activities together with global partners.

For more information about Eisai, please visit www.eisai.com (for global headquarters: Eisai Co., Ltd.), us.eisai.com (for U.S. headquarters: Eisai, Inc.) or www.eisai.eu (for Europe, Middle East, Africa, Russia, Australia, and New Zealand headquarters: Eisai Europe Ltd.), and connect with us on Twitter ([U.S.](#) and [global](#)) and [LinkedIn](#) (for [U.S.](#) and [EMEA](#)).

Forward-Looking Statements

This press release contains forward-looking statements. Forward-looking statements involve known and unknown risks and uncertainties, which may cause Catalyst's actual results in future periods to differ materially from forecasted results. A number of factors, including (i) whether the proposed acquisition of FYCOMPA® will be completed, (ii) whether the acquisition transaction, if completed, will prove to be accretive, (iii) whether Catalyst and Eisai will successfully negotiate a mutually acceptable arrangement for Catalyst to acquire one of Eisai's late stage products under development from its rare epilepsy portfolio, (iv) whether, if the acquisition transaction is completed, Catalyst can successfully integrate the FYCOMPA business into its business activities, and (v) those factors described in Catalyst's Annual Report on Form 10-K for the 2021 fiscal year, Catalyst's Quarterly Report on Form 10-Q for the third quarter of 2022, and Catalyst's other filings with the SEC, could adversely affect Catalyst. Copies of Catalyst's filings with the SEC are available from the SEC, may be found on Catalyst's [website](#), or may be obtained upon request from Catalyst. Catalyst does not undertake any obligation to update the information contained herein, which speaks only as of this date.

About Epilepsy

Epilepsy is a medical condition that produces seizures affecting a variety of mental and physical functions. Epilepsy is one of the most common neurological disorders, which affects 3.4 million people in the United States, including 470,000 children. Children with uncontrolled seizures are at greater risk for sudden unexpected death in epilepsy (SUDEP), which is relatively uncommon in childhood, but the risk increases if epilepsy persists into adulthood.

Partial-onset seizures are the most common types of seizures seen in people with epilepsy, accounting for 60 percent of all seizures. Convulsive seizures account for up to 25 percent of all epilepsy, with primary generalized tonic-clonic seizures being one of the most common and severe forms of seizures.

Missed medication doses are the number one cause of breakthrough seizures, which can cause significant injury to patients. People who experience breakthrough seizures have an increased risk of fractures or head injuries, emergency room (ER) visits, and hospitalization, as well as associated increase in healthcare costs.

About FYCOMPA

FYCOMPA is a prescription medicine used in people with epilepsy aged 4 and older alone or with other medicines to treat partial-onset seizures with or without secondarily generalized seizures, and with other medicines to treat primary generalized tonic-clonic seizures for people with epilepsy aged 12 and older.

FYCOMPA, an oral medication, is a selective non-competitive AMPA (alpha-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid) receptor antagonist. The precise mechanism by which FYCOMPA exerts its antiepileptic effects in humans is unknown.

FYCOMPA is supplied as 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg film-coated tablets, and as a 0.5 mg/mL oral suspension formulation. FYCOMPA has been designated by the U.S. Drug Enforcement Administration as a federally-controlled substance (CIII). To date, FYCOMPA has been prescribed to over 500,000 patients globally.

Important Safety Information: INDICATION FOR FYCOMPA

FYCOMPA® (perampanel) is indicated in patients with epilepsy aged 4 years and older for partial-onset seizures (POS) with or without secondarily generalized seizures and adjunctive therapy for patients aged 12 years and older for primary generalized tonic-clonic (PGTC) seizures.

IMPORTANT SAFETY INFORMATION FOR FYCOMPA**WARNING: SERIOUS PSYCHIATRIC AND BEHAVIORAL REACTIONS**

- Serious or life-threatening psychiatric and behavioral adverse reactions including aggression, hostility, irritability, anger, and homicidal ideation and threats have been reported in patients taking FYCOMPA
- These reactions occurred in patients with and without prior psychiatric history, prior aggressive behavior, or concomitant use of medications associated with hostility and aggression
- Advise patients and caregivers to contact a healthcare provider immediately if any of these reactions or changes in mood, behavior, or personality that are not typical for the patient are observed while taking FYCOMPA or after discontinuing FYCOMPA
- Closely monitor patients particularly during the titration period and at higher doses
- FYCOMPA should be reduced if these symptoms occur and should be discontinued immediately if symptoms are severe or are worsening

SERIOUS PSYCHIATRIC AND BEHAVIORAL REACTIONS

In the partial-onset seizures clinical trials, hostility- and aggression-related adverse reactions occurred in 12% and 20% of patients randomized to receive FYCOMPA at doses of 8 mg and 12 mg per day, respectively, compared to 6% of patients in the placebo group. These effects were dose-related and generally appeared within the first 6 weeks of treatment, although new events continued to be observed through more than 37 weeks. These effects in FYCOMPA-treated patients led to dose reduction, interruption, and discontinuation more frequently than placebo-treated patients. Homicidal ideation and/or threat have also been reported postmarketing in patients treated with FYCOMPA. The combination of alcohol and FYCOMPA significantly worsened mood and increased anger. Patients taking FYCOMPA should avoid the use of alcohol. Patients, their caregivers, and families should be informed that FYCOMPA may increase the risk of psychiatric events. Patients should be monitored during treatment and for at least one month after the last dose of FYCOMPA, and especially when taking higher doses and during the initial few weeks of drug therapy (titration period) or at other times of dose increases. Similar serious psychiatric and behavioral events were observed in the primary generalized tonic-clonic (PGTC) seizure clinical trial.

SUICIDAL BEHAVIOR AND IDEATION

Antiepileptic drugs (AEDs), including FYCOMPA, increase the risk of suicidal thoughts or behavior in patients. Anyone considering prescribing FYCOMPA or any other AED must balance the risk of suicidal thoughts or behavior with the risk of untreated illness. Epilepsy and many other illnesses for which AEDs are prescribed are themselves associated with morbidity and mortality and an increased risk of suicidal thoughts and behavior. Patients, their caregivers, and families should be informed of the risk and advised to monitor and immediately report the emergence or worsening of depression, suicidal thoughts or behavior, thoughts about self-harm and/or any unusual changes in mood or behavior. Should suicidal thoughts and behavior emerge during treatment, consider whether the emergence of these symptoms in any given patient may be related to the illness being treated.

DIZZINESS AND GAIT DISTURBANCE

FYCOMPA caused dose-related increases in events related to dizziness and disturbance in gait or coordination. Dizziness and vertigo were reported in 35% and 47% of patients in the partial-onset seizure trials randomized to receive FYCOMPA at doses of 8 mg and 12 mg per day, respectively, compared to 10% of placebo-treated patients. Gait disturbance related events were reported in 12% and 16% of patients in the partial-onset seizure clinical trials randomized to receive FYCOMPA at doses of 8 mg and 12 mg per day, respectively, compared to 2% of placebo-treated patients. These adverse reactions occurred mostly during the titration phase. These adverse reactions were also observed in the PGTC seizure clinical trial.

SOMNOLENCE AND FATIGUE

FYCOMPA caused dose-dependent increases in somnolence and fatigue-related events. Somnolence was reported in 16% and 18% of patients in the partial-onset seizure trials randomized to receive FYCOMPA at doses of 8 mg and 12 mg per day, respectively, compared to 7% of placebo-treated patients. Fatigue-related events were reported in 12% and 15% of patients in the partial-onset seizure trials randomized to receive FYCOMPA at doses of 8 mg and 12 mg per day, respectively, compared to 5% of placebo-treated patients. These adverse reactions occurred mostly during the titration phase. These adverse reactions were also observed in the PGTC seizure clinical trial. Patients should be advised against engaging in hazardous activities requiring mental alertness, such as operating motor vehicles or dangerous machinery, until the effect of FYCOMPA is known. Patients should be carefully observed for signs of central nervous system (CNS) depression when FYCOMPA is used with other drugs with sedative properties because of potential additive effects.

FALLS

Falls were reported in 5% and 10% of patients in the partial-onset seizure clinical trials randomized to receive FYCOMPA at doses of 8 mg and 12 mg per day, respectively, compared to 3% of placebo-treated patients.

DRUG REACTION WITH EOSINOPHILIA AND SYSTEMIC SYMPTOMS (DRESS)

DRESS, also known as multiorgan hypersensitivity, has been reported in patients taking AEDs, including FYCOMPA. DRESS may be fatal or life-threatening. DRESS typically, although not exclusively, presents with fever, rash, lymphadenopathy, and/or facial swelling, in association with other organ system involvement. If signs or symptoms are present, immediately evaluate the patient and discontinue FYCOMPA if an alternative etiology for signs or symptoms cannot be established.

WITHDRAWAL OF AEDs

A gradual withdrawal is generally recommended with AEDs to minimize the potential of increased seizure frequency, but if withdrawal is a response to adverse events, prompt withdrawal can be considered.

MOST COMMON ADVERSE REACTIONS

The most common adverse reactions in patients aged 12 years and older receiving FYCOMPA ($\geq 5\%$ and $\geq 1\%$ higher than placebo) include dizziness, somnolence, fatigue, irritability, falls, nausea, weight gain, vertigo, ataxia, headache, vomiting, contusion, abdominal pain, and anxiety. Adverse reactions in patients aged 4 to <12 years were generally similar to patients aged 12 years and older.

DRUG INTERACTIONS

FYCOMPA may decrease the efficacy of contraceptives containing levonorgestrel. Plasma levels of perampanel were decreased when administered with known moderate and strong CYP3A4 inducers, including, carbamazepine, phenytoin, or oxcarbazepine. Multiple dosing of FYCOMPA 12 mg per day enhanced the effects of alcohol on vigilance and alertness, and increased levels of anger, confusion, and depression. These effects may also be seen when FYCOMPA is used in combination with other CNS depressants.

PREGNANCY AND LACTATION

Physicians are advised to recommend that pregnant patients taking FYCOMPA enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry. Caution should be exercised when FYCOMPA is administered to pregnant or nursing women as there are no adequate data on the developmental risk associated with use in pregnant women, and no data on the presence of perampanel in human milk, the effects on the breastfed child, or the effects of the drug on milk production.

HEPATIC AND RENAL IMPAIRMENT

Use in patients with severe hepatic or severe renal impairment is not recommended. Dosage adjustments are recommended in patients with mild or moderate hepatic impairment. Use with caution in patients with moderate renal impairment.

DRUG ABUSE AND DEPENDENCE

FYCOMPA is a Schedule III controlled substance and has the potential to be abused and lead to drug dependence and withdrawal symptoms including anxiety, nervousness, irritability, fatigue, asthenia, mood swings, and insomnia.

Please see full **Prescribing Information**, including Boxed WARNING.

Source: Catalyst Pharmaceuticals, Inc.

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