

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549
FORM 8-K

CURRENT REPORT

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

January 6, 2022 (December 31, 2021)
Date of Report (date of earliest event reported)

CUMBERLAND PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

Tennessee
(State or other jurisdiction of incorporation or organization)

001-33637
(Commission File Number)

62-1765329
(IRS Employer Identification No.)

2525 West End Avenue, Suite 950 Nashville, Tennessee 37203

(Address of Principal Executive Offices) (Zip Code)

(615) 255-0068

Registrant's telephone number, including area code

Not Applicable

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

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

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each Class	Trading Symbol	Name of each exchange on which registered
Common stock, no par value	CPIX	Nasdaq Global Select Market

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

Emerging growth company

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

Item 1.01 Entry into a Material Definitive Agreement

On December 31, 2021, Cumberland Pharmaceuticals Inc. (the “Company” or “Cumberland”) signed and entered into a definitive agreement (the “Agreement”) to acquire the U.S. rights to SANCUSO® (the “Product”) from Kyowa Kirin, Inc. (“Kyowa Kirin” or “Sellers”). Cumberland Pharmaceuticals Inc. is a specialty pharmaceutical company focused on the delivery of high-quality, prescription brands designed to improve patient care. Kyowa Kirin, Inc. is a global specialty pharmaceutical company that strives to create and deliver novel medicines with life-changing value.

SANCUSO® is the first and only FDA-approved prescription patch for the prevention of nausea and vomiting in patients receiving certain types of chemotherapy treatment. The active drug in SANCUSO®, granisetron, slowly dissolves in the thin layer of adhesive that sticks to the patient’s skin and is released into their bloodstream over several days, working continuously to prevent chemotherapy-induced nausea and vomiting (CINV).

Under the terms of the Agreement, Cumberland acquired the U.S. rights to SANCUSO® and assumed full commercial responsibility for the product – including its marketing, promotion, distribution, manufacturing and medical support activities. Net sales of the brand in the U.S. were over \$14 million in 2020.

The financial terms of the acquisition included a \$13.5 million payment to Kyowa Kirin upon closing, up to \$3.5 million in milestones and tiered royalties ranging from 10% to 5% on U.S. net product sales for ten years. Kyowa Kirin will retain international rights, continuing to deliver the product to address oncology patients’ needs throughout the rest of the world.

The Agreement contains customary representations, warranties and covenants, as well as indemnification provisions.

The foregoing summary of the Agreement does not purport to be complete and is subject to, and qualified in its entirety by, the complete text of the Agreement, dated as of December 31, 2021, which is filed herewith as Exhibit 2.1 and incorporated herein by reference.

Item 2.01 Completion of Acquisition or Disposition of Assets

On January 3, 2022, Cumberland completed the purchase (the “Transaction”) from Kyowa Kirin pursuant to which the Company acquired the U.S. rights from Sellers assets related to the marketing, promotion, distribution, manufacturing and medical support for SANCUSO® as it relates to the Agreement signed by Cumberland and the Sellers dated December 31, 2021.

Upon closing the Transaction, Cumberland paid an initial payment of \$13.5 million to Sellers. Cumberland used funds from its Revolving Credit Loan with Pinnacle Bank to fund the initial payment. The remainder of the purchase price will be paid to Sellers through milestone payments up to \$3.5 million and tiered royalties up to 10% on future U.S. net sales of the Product.

The information set forth under Item 1.01 of this Current Report on Form 8-K is incorporated herein by reference insofar as it relates to the Transaction.

Item 7.01 Regulation FD Disclosure

On January 4, 2022, Cumberland issued a press release announcing the Agreement to acquire the U.S. rights to SANCUSO® from Kyowa Kirin. A copy of the press release is furnished and attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference in the Item 7.01.

The information furnished pursuant to Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section, nor shall it be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such future filing that such information is to be considered “filed” or incorporated by reference therein.

Item 9.01 Financial Statements and Exhibits

(a) Financial Statements of Business Acquired

Any financial statements to be filed in response to this Item 9.01(a) with respect to the transactions described in Item 2.01 will be filed by amendment to this Current Report on Form 8-K not later than 71 calendar days after the date on which this Current Report on Form 8-K must be filed.

(b) Pro Forma Financial Information

Any pro forma financial information to be filed in response to this Item 9.01(b) with respect to the transactions described in Item 2.01 will be filed by amendment to this Current Report on Form 8-K not later than 71 calendar days after the date on which this Current Report on Form 8-K must be filed.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated January 4, 2022
2.1*	Asset Purchase Agreement, dated December 31, 2021, by and among Cumberland Pharmaceuticals Inc. and Kyowa Kirin, Inc., +*

* Schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule will be furnished supplementally to the U.S. Securities and Exchange Commission upon request, provided, however, that the parties may request confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended for any document so furnished.

SIGNATURES

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

Dated: January 6, 2022

Cumberland Pharmaceuticals Inc.

By:

/s/ John Hamm

John Hamm

Chief Financial Officer

ASSET PURCHASE AGREEMENT

This ASSET PURCHASE AGREEMENT (this “Agreement”) is effective as of the 31st day of December 2021 (the “Effective Date”), by and among Kyowa Kirin, Inc., a corporation incorporated in the State of Delaware, having a principal place of business at 135 Route US-202, Suite 6, Bedminster, NJ 07921 (“KKUS”) and Cumberland Pharmaceuticals Inc., a corporation incorporated in the State of Tennessee, having a principal place of business at 2525 West End Avenue, Suite 950, Nashville, Tennessee (“Cumberland”). Cumberland and KKUS are referred to hereinafter individually as a “Party” and together as the “Parties.” Capitalized terms used herein shall be as defined in this Agreement.

RECITALS

WHEREAS, KKUS wishes to sell to Cumberland, and Cumberland wishes to acquire the certain assets of KKUS related to the pharmaceutical product known as Sancuso[®], and

WHEREAS, the Parties entered into a Non-Binding Term Sheet dated December 9, 2021, and this Agreement is intended to be the Definitive Agreement of the Parties with respect to the matters included said Non-Binding Term Sheet.

NOW, THEREFORE, in consideration of the mutual agreements and covenants contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE I DEFINITIONS

Section 1.1 As used in this Agreement, the following terms shall have the meanings ascribed to them below:

(a) “Affiliate” means, with respect to any Person (as defined herein), any other Person that directly or indirectly Controls, is Controlled by or is under common Control with such first Person. A Person will be deemed to “Control” another Person if such first Person has (i) direct or indirect ownership of more than fifty percent (50%) of the equity (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) having the power to vote on or direct the affairs of such other Person, or (ii) the power, directly or indirectly, to direct or cause the direction of the policies and management of the other Person, whether by the ownership of stock, by contract, or otherwise.

(b) “Assets” shall mean all right, title, and interest in and to the Product (as defined herein) in the Territory (as defined herein) as of the Effective Date, except as changed in the ordinary course of doing business through the Closing Date, including but not limited to, Intellectual Property and IP Rights (as defined herein), Inventory, Contracts (as defined herein), Marketing and Promotional Literature (as defined herein), and all assets used in, beneficial to, incidental to, resulting from, related to, or otherwise associated with the Product, whether tangible, intangible, personal or real and wherever located and by whomever possessed in the Territory as further delineated in Schedules A-1 to A-5 to Exhibit A attached hereto. For the avoidance of doubt, the Assets shall not include the NDA (as defined herein) until the NDA Transfer Date (as defined herein). Thereafter, Assets shall include the NDA and all clinical and non-clinical data, FDA registration files and registrations related to the Product in the Territory.

(c) “Assumed Liability(ies)” shall mean no liability not expressly identified and stated on Exhibit B attached hereto, excluding the obligation of Cumberland to issue U.S. Certificates of Pharmaceutical Product (“CPP”) after the NDA Transfer Date.

(d) “Business Day” means any day other than a Saturday, Sunday, or other day that is a United States of America federal holiday.

(e) “Closing” and “Closing Date” shall mean January 3, 2022, or any other date as KKUS and Cumberland shall agree.

(f) “Contracts” means contracts, leases, indentures, agreements, purchase orders and all other legally binding arrangements, including all amendments thereto, in effect as of the Closing Date with respect to the Product in the Territory, including the Kindeva Manufacturing and Supply Agreement effective August 31, 2021 and the Asembia Master Services Agreement effective April 11, 2019 and the SOWs entered into thereunder, all as identified on “Schedule A-2” attached hereto.

(g) “FDA” means the United States Food & Drug Administration, being a federal agency of the United States Department of Health and Human Services, which is responsible for, amongst other things, the evaluations of, and the protecting and promoting of public health through the control and supervision of, pharmaceutical drugs, and all divisions under its direct control or any successor organizations.

(h) “Governmental Authority(ies)” means any federal, national, state or local governmental authority, court, commission, regulatory, administrative or other agency, department, political or other subdivision, or instrumentality, or branch of any of the foregoing in the Territory which regulates the development, manufacture, marketing, promotion, pricing, reimbursement, and or sale of pharmaceutical products in the Territory.

(i) “Gross Sales” shall mean the total revenues and receipts from the sale of Product in the Territory.

(j) “Intellectual Property” means all inventions, all rights to inventions, patents, patent applications and issued patents, proprietary formulations, market information and plans, designs, design applications and design registrations, trademarks, trade mark applications, trade mark registration, trade names, trade dresses, service marks, logos (whether registered or unregistered), copyright, copyright applications and registrations, and all other intellectual property relating to the Product now or hereafter owned, whether or not reduced to writing, held or used by KKUS, or any of its Affiliates (including any goodwill associated with such trademarks and registrations thereof), trade dress rights, trade names, internet domain names, internet and web URL or addresses, copyrights, copyright registrations and applications therefor, and Know-How, applicable to the Product in the Territory as identified on “Schedule A-3” attached hereto, including all applicable rights arising out of or related thereto (“IP Rights”).

(k) “Know-How” means all technology, trade secrets, technical data, manufacturing information, pre-clinical and clinical data, sales data and any other information or experience (other than as disclosed in the Patent Rights) specifically related to Sancuso and the Product in the Territory.

(l) “Loss” or “Losses” means any actual losses, damages, liabilities, costs, or expenses.

(m) “Marketing and Promotional Literature” shall mean all KKUS English language descriptive literature, advertising materials, technical manuals and sales promotional materials concerning the Product in the Territory in inventory as of the Closing Date as identified on “Schedule A-4” attached hereto.

(n) “Material Adverse Effect” means a change, circumstance or effect that has had or would reasonably be expected to have a material adverse effect on (i) the Product or the Assets, taken as a whole, or (ii) the ability of KKUS to timely consummate the transactions contemplated by this Agreement, except, in each case, to the extent such change, circumstance, event or effect is reasonably attributable solely to: (A) the announcement of or consummation of the transaction contemplated by this Agreement or the other transaction documents; (B) changes in general economic conditions, the financial markets or the pharmaceuticals industry generally; or (C) changes caused by a material worsening of current conditions caused by acts of terrorism or war (whether or not declared) occurring after the date hereof.

(o) “Net Sales” shall mean Cumberland’s Gross Sales of the Product in the Territory less the following deductions but only to the extent included in Gross Sales and determined in each case in accordance with generally accepted accounting principles in the United States of America (“U.S. GAAP”):

(i) normal and customary trade and quantity discounts, fees for service, coupon discounts actually allowed and properly taken directly with respect to sales of such Product;

(ii) credits or allowances given or made for rejection or returns of previously sold Products (expired, short-dated, damaged, or returned) or for retroactive price reductions and billing errors;

(iii) rebates and chargeback payments, Medicare Part D Allowances, Medicaid Allowances, granted to managed health care organizations, pharmacy benefit managers (or equivalents thereof), national, state/provincial, local, and other Government Authorities including, their agencies and purchasers and reimbursers, wholesalers, or to trade customers; and

(iv) gross sales offsets provided to specialty pharmacies, warehousing chains or distributors for their services provided.

(v) For purposes of determining Net Sales, a Product will be deemed to be sold when invoiced. A particular deduction may only be accounted for once in the calculation of Net Sales.

(p) “NDA” means collectively, the United States New Drug Application Number N022198, including all documents, data, and other information concerning the Product necessary therefor, required for regulatory approval of a pharmaceutical product by the FDA and the corresponding NDA Approval by the FDA (“NDA Approval”).

(q) “NDA Transfer Date” has the meaning set forth in Section 2.2.

(r) “Person” means any individual, corporation, partnership, limited liability company, joint venture, trust, business association, organization, or other entity.

(s) “Product” means Sancuso[®] a medicine containing granisetron, a serotonin-3 (5-HT3) receptor antagonist sold under the NDA and including any supplements thereto, in all FDA approved forms and indications, the chemical structure of which is shown in “Schedule A-1” attached hereto.

(t) “Product Records” means the books, documents, records, and files exclusively related to the Product in the Territory, but excluding lab notebooks.

(u) “Product Regulatory Materials” means all written notices, submissions, reports, documentation, medical letters, the Product safety database, and correspondence between KKUS, on the one hand, and Governmental Authorities in the Territory, including the FDA, on the other hand, in each case only to the extent the material (i) is necessary for the development, manufacture, distribution, marketing or sale of the Product in the Territory as such activities are conducted by KKUS as of sixty (60) days prior to the Effective Date, (ii) relates solely to the NDA or the Product, and (iii) is maintained by or otherwise in the possession of KKUS as of the Closing Date or which are received by KKUS subsequent to the Closing Date.

(v) “Territory” means the United States of America and its territories and possessions.

(w) “Third Party” means any Person other than Cumberland, KKUS, or their respective Affiliates.

Section 1.2 Interpretation.

(a) When used in this Agreement, the words “include,” “includes” and “including” shall be deemed to be followed by the words “without limitation.”

(b) Any terms defined in the singular shall have a comparable meaning when used in the plural, and vice-versa.

(c) This Agreement shall be deemed drafted jointly by Cumberland and KKUS and shall not be specifically construed against either Party based on any claim that such Party or its counsel drafted this Agreement.

Section 1.3 Currency. All currency amounts referred to in this Agreement are in United States Dollars (“USD”) unless otherwise specified.

ARTICLE II
SALE AND PURCHASE OF ASSETS; NDA LICENSE;
TRANSITION SERVICES

Section 2.1 Sale and Purchase of Assets. Upon the terms and subject to the conditions of this Agreement, on the Closing Date (as defined herein), KKUS (or its designated Affiliates) shall sell, assign, transfer, convey and deliver (or, where relevant, shall procure the same) to Cumberland (or its designated Affiliates) free and clear of all encumbrances (other than Assumed Liabilities) and Cumberland (or its designated Affiliates) shall purchase, acquire and accept, all right, title and interest of KKUS in, to and under the Assets. For the avoidance of doubt, the Assets shall not include the NDA until the NDA Transfer Date, as set forth in Section 2.2 below, the Excluded Assets as defined in Section 2.8, and copies of Product Records, Product Regulatory Materials and Marketing and Promotional Material retained by KKUS to comply with its legal obligations.

Section 2.2 NDA and IND Transfers. KKUS will continue to hold the NDA for the Product until such time as the licensees, and associated territories, must no longer rely on the NDA. When this occurs, KKUS shall promptly transfer all of its right, title, and interest in and to the NDA to Cumberland (the “NDA Transfer Date”) as the final step in the sale and purchase of Assets pursuant to this Agreement. Prior to the NDA Transfer Date, KKUS shall license the NDA to Cumberland as forth in Section 2.4 below. KKUS will continue to hold the IND until such time as the FDA required Bioequivalence/Adhesion study and all associated interactions with FDA have been completed. When this occurs, KKUS shall promptly transfer all of its right, title, and interest in and to the IND to Cumberland (the “IND Transfer Date”). After the later of the IND Transfer Date and the NDA Transfer Date, the Assets shall include the NDA and all clinical and non-clinical data, and FDA files and registrations related to the Product in the Territory. KKUS shall be entitled to retain copies of the NDA, the IND, Product Records, Product Regulatory Materials and Marketing and Promotional Material in order to comply with its legal obligations.

Section 2.3 Assumed Liabilities. Subject to the terms and conditions of this Agreement, Cumberland will assume, be responsible for and pay, perform and/or otherwise discharge when due the Assumed Liabilities. It is expressly understood and agreed that Cumberland shall not assume any liabilities of KKUS other than the Assumed Liabilities. All other liabilities of every form and nature, shall be retained by and remain liabilities, obligations, and commitments of KKUS. KKUS shall assume and shall pay, perform, and discharge when due all other liabilities, encumbrances, liens, or obligations, directly or indirectly, associated with the Assets. For the avoidance of doubt, no post-marketing obligations (including with respect to pediatric patients) with respect to the Product imposed by the FDA or other Governmental Authority are Assumed Liabilities.

Section 2.4 NDA License Agreement Term. From the Closing Date until the NDA Transfer Date, KKUS hereby grants to Cumberland the exclusive right to promote, market, transfer, distribute and/or sell the Product in the Territory in reliance upon the NDA and Cumberland agrees to use commercially reasonable efforts to promote, market, transfer, distribute and/or sell the Product in the Territory in compliance with the NDA and laws applicable thereto, and to conduct its business in a manner that reflects favorably at all times on the Product. During said period, KKUS shall maintain the NDA in full force and effect and in good standing in compliance with FDA requirements and all applicable laws.

Section 2.5 Transition Services and Activities. The Parties shall cooperate in good faith in transitioning the Product and related arrangements following the Closing, including the Kindeva Manufacturing and Supply Agreement, a copy of which is attached hereto in Schedule A-2. The Parties shall each bear their own costs associated with any services and activities they are required to handle pursuant to this Agreement as set forth on Exhibit C attached hereto. Within a reasonable time following the Closing Date, the Parties shall negotiate and mutually agree to and execute the following additional Agreements: (i) Quality Agreement, and (ii) Pharmacovigilance Agreement.

Section 2.6 Governance and Decision Making. The Parties shall form a joint steering committee (“JSC”) for key decision-making to ensure a successful Product transition, including joint review of promotional materials during the NDA License Agreement Term. The Parties may also form subcommittees, such as a joint manufacturing committee, to support discussion and decision making at JSC as necessary with regard to specific issues. The JSC shall meet either in person or virtually at least once per calendar year. The JSC shall include at least two (2) representatives from each Party. Notwithstanding the foregoing, all Product release decisions shall be made by KKUS during the NDA License Agreement Term.

Section 2.7 Personnel. As of the Effective Date, KKUS employs three (3) individuals who sell the Product; specifically, a national sales manager and two sales representatives. Subject to applicable laws and Cumberland policies, Cumberland shall extend a formal job offer letter to these three (3) individuals for similar roles at Cumberland, including base pay, sales territories and incentive compensation targets. These three KKUS employees will have seven (7) days to consider the job offers and provide their formal response to Cumberland.

Section 2.8 Excluded Assets. KKUS shall not sell, transfer, convey, assign or deliver to Cumberland, and Cumberland shall not purchase, acquire and accept from KKUS pursuant to this Agreement or any ancillary agreement, and KKUS and its Affiliates shall retain following the Closing Date, the Excluded Assets. As used in this Agreement, “Excluded Assets” means all assets, property, rights and interests of KKUS and its Affiliates other than the Assets, including:

- (a) all intellectual property and rights thereto and therein of KKUS and its Affiliates other than the Intellectual Property;
- (b) all tangible personal property of the Sellers or any of their respective Affiliates, except as included in Assets;
- (c) all KKUS accounts receivable;
- (d) all refunds, claims for refunds or rights to receive refunds from any taxing authority with respect to taxes related to the Product incurred prior to the Closing;
- (e) all insurance policies and insurance contracts insuring the Assets, together with any claim, action or other right KKUS or any of its Affiliates may have for insurance coverage under any past or present policies and insurance contracts insuring the Assets or KKUS business and personnel;
- (f) all guarantees, warranties, indemnities and similar rights that have been made by any predecessors in title, manufacturers or suppliers and other Third Parties relating to the Excluded Assets described in this section;
- (g) all claims, counterclaims, defenses, causes of action, rights of recovery, rights of set-off, rights of subrogation and all other rights of any kind against any Third Party to the extent related to the Excluded Assets described in this section, in each case whether arising before, at or after the Closing;
- (h) all real property and interests therein owned by KKUS;
- (i) all cash and cash equivalents;

(j) copies of Product Records, Product Regulatory Materials and Marketing and Promotional Material retained by KKUS to comply with its legal obligations; and

(k) all books and records of KKUS and its Affiliates that are not Product Records.

ARTICLE III
PURCHASE PRICE

Section 3.1 Purchase Price. Subject to the terms and conditions set forth herein, in consideration of the sale, assignment, conveyance, and delivery of the Assets, the NDA License, and assumption of the Assumed Liabilities, Cumberland will pay to KKUS:

(a) thirteen million five-hundred thousand and no/100 dollars (USD \$13,500,000.00) upon Closing (the “Upfront Payment”); and

(b) each of the following milestone payments (each, a “Milestone Payment”):

(i) one million and no/100 dollars (USD \$1,000,000.00) upon successful technology transfer and FDA approval of manufacture of the Product for sale and distribution in the Territory from the current Kindeva manufacturing facility in Minnesota to Kindeva’s Northridge, California manufacturing facility;

(ii) five-hundred thousand and no/100 dollars (USD \$500,000.00) upon completion of the successful transfer of the NDA to Cumberland;

(iii) a one-time payment of two million and no/100 dollars (USD \$2,000,000.00) upon Cumberland’s first achievement of twenty million and no/100 dollars (USD \$20,000,000.00) in annual Net Sales.

(c) the Net Sales Royalty (as defined, and in accordance with Section 3.2).

Section 3.2 Net Sales Royalty.

(a) Commencing on the Closing Date and continuing for a period of ten (10) years thereafter (the “Royalty Term”), Cumberland shall make royalty payments to KKUS on Net Sales of Product in accordance with the table below:

Net Sales Range	Royalty Rate (% of Net Sales)
From the Closing Date until expiration of all valid Territory patents covering the Product.	10%
From expiration of all valid Territory patents covering the Product through generic entry of the Product	5%

Section 3.3 Calculation and Payment. Within thirty (30) days’ after the end of each quarter following the Closing Date, Cumberland shall report to KKUS Gross Sales for the preceding quarter (“Quarterly Gross Sales Report”). Within sixty (60) days’ after the end of each quarter following the Closing Date, Cumberland shall report to KKUS Net Sales for the preceding quarter (a “Quarterly Net Sales Report”). Each such Quarterly Net Sales Report shall specify in reasonable detail all deductions allowed in the calculation of such Net Sales. Each Net Sales Royalty Payment shall be paid to KKUS

within sixty (60) days' after the end of each quarter during the Royalty Term with respect to Net Sales in such quarter. Cumberland shall make the foregoing reports via email to KKUS Attn: Chris Kazlauskas, CPA, Controller, at Chris.kazlauskas.3n@kyowakirin.com.

Section 3.4 Manner and Place of Payment. All payments owed under this Agreement shall be made by wire transfer to the banks and accounts designated in writing by KKUS, unless otherwise specified in writing by KKUS.

Section 3.5 Non-Compete. During the Royalty Term and for a period of one (1) year thereafter, neither Party shall market in the Territory any product that is directly competitive with the Product.

Section 3.6 Transfer of Manufacturing Operations. As further consideration for the Assets pursuant to this Agreement, KKUS shall continue commercially reasonable efforts to obtain FDA approval, including conducting any FDA required Bioequivalence/Adhesion study results, for a Product manufacturing site change from the Kindeva Minnesota manufacturing site to the Kindeva Northridge, California manufacturing site. If said FDA approval is not obtained on or about December 22, 2022, to seek approval and to conduct required studies as required by the FDA to obtain approval of the new Kindeva manufacturing site for the Product. All legal, consulting and regulatory related expenses that can be documented by Cumberland as incurred by Cumberland in obtaining such approval and conducting said studies shall be deducted from Cumberland payments of Net Sales Royalties, dollar for dollar, against Cumberland Net Sale Royalty obligations pursuant to this Agreement. This offsetting of costs shall constitute the sole remedy to Cumberland in the event that KKUS fails to obtain FDA approval within a reasonable timeframe.

Section 3.7 Risk of Loss. As of the Closing, title to the Assets shall be transferred to Cumberland.

ARTICLE IV THE CLOSING

Section 4.1 Closing Date. Pursuant to the terms and subject to the conditions of this Agreement, the Closing of the transactions contemplated hereby shall occur on or before the Closing Date. The Closing, and the transfer of the Assets, Assumed Liabilities, and NDA License, shall be deemed to be effective as of 11:59 p.m. Central Time on the Closing Date.

Section 4.2 Closing Activities.

(a) At the Closing, payment of the Upfront Payment by Cumberland to KKUS shall be made by Cumberland.

(b) At the Closing, KKUS will sell, assign, convey and transfer (or, where relevant, shall procure the same) to Cumberland or, as directed by Cumberland, to Cumberland's Affiliate, all KKUS's and any of KKUS's Affiliates right, title, and interest in, to and under the Assets free and clear of all encumbrances (other than the Assumed Liabilities).

(c) At or prior to the Closing, KKUS shall deliver or cause to be delivered to Cumberland, or to an Affiliate as directed by Cumberland, a copy of the NDA in eCTD format.

(d) At Closing, KKUS shall have executed and delivered to Cumberland all Contracts that are freely assignable, as applicable and in customary form, as necessary or required by the terms of this Agreement, the Contracts, or Cumberland.

(e) At Closing, KKUS shall provide Cumberland with hard copies of (if any) and electronic files, including those for printing dimensional PDFs for production, containing the Marketing and Promotional Literature which shall be used by Cumberland solely as a reference to Cumberland as it develops Cumberland's own promotional materials in connection with the commercialization of the Product.

(f) At Closing, KKUS shall deliver to Cumberland a certificate, duly executed by an authorized officer of KKUS, certifying that the representations and warranties of such KKUS contained in Article V are true and correct in all material respects as of the Closing Date (except as qualified by materiality or Material Adverse Effect, in which case they shall be true and correct in all respects) with the same effect as though made at and as of such date (except those representations and warranties that address matters only as of a specified date, which shall be true and correct in all material respects as of that specified date) and that KKUS has duly performed and complied in all material respects with all agreements, covenants and conditions required by this Agreement to be performed or complied with by KKUS prior to or on the Closing Date.

(g) At Closing, Cumberland shall deliver to KKUS a certificate, duly executed by an authorized officer of Cumberland, certifying that the representations and warranties of Cumberland contained in Article VI are true and correct in all material respects as of the Closing Date (except as qualified by materiality or Material Adverse Effect, in which case they shall be true and correct in all respects) with the same effect as though made at and as of such date (except those representations and warranties that address matters only as of a specified date, which shall be true and correct in all material respects as of that specified date) and that Cumberland has duly performed and complied in all material respects with all agreements, covenants and conditions required by this Agreement to be performed or complied with by Cumberland prior to or on the Closing Date.

(h) At Closing, Cumberland and KKUS shall deliver to the other Party such other documents, instruments and certificates as may be reasonably requested by such Party in order to further evidence the transactions contemplated by this Agreement and to vest in Cumberland all rights, title and interest in and to the Assets pursuant to the terms of this Agreement.

Section 4.3 Further Assurances. KKUS and Cumberland agree that at any time or from time to time after the Closing, each Party, at the request and expense of the other, shall within fifteen (15) days' execute and deliver to the other Party all such instruments and documents or further ministerial assurances as the other Party may reasonably request that are necessary in order to transfer to Cumberland KKUS's right, title, and interest in and to the Assets and all approvals and permits as contemplated hereby and to otherwise consummate all of the transactions contemplated by this Agreement, including but not limited to bills of sale, and patent, trademark, and contractual assignments related to the Assets and FDA required transfer of ownership letters or documentation to effectuate the transfer of ownership of the NDA upon the NDA Transfer Date.

ARTICLE V REPRESENTATIONS AND WARRANTIES OF SELLER

KKUS hereby represents and warrants to Cumberland as of the date hereof, as follows:

Section 5.1 Organization; Good Standing. KKUS is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its formation. KKUS has all requisite power and authority to carry on its business as it is currently being conducted. KKUS is duly qualified to conduct business and is in good standing in every jurisdiction in the Territory where the nature of the business conducted by it makes such qualification necessary, except where the failure to so qualify or be in good standing would not result in a Material Adverse Effect.

Section 5.2 Authority; Execution and Delivery. KKUS has the requisite power and authority to enter into this Agreement, including any approvals required by its Parent or Affiliates, and the other transaction documents and to consummate the transactions contemplated hereby and thereby. The execution and delivery of this Agreement and the other transaction documents by KKUS and the consummation of the transactions contemplated hereby and thereby have been duly and validly authorized and no additional

corporate or shareholder authorization or consent is required in connection with the execution, delivery and performance by KKUS of this Agreement and the other transaction documents. This Agreement and the transaction documents have been duly executed and delivered by KKUS and, assuming the due authorization, execution and delivery of this Agreement and the transaction documents by Cumberland, will constitute legal, valid and binding obligations of KKUS, enforceable against it in accordance with their terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent transfer and other similar laws affecting creditors' rights generally from time to time in effect and to general principles of equity regardless of whether considered in a proceeding in equity or at law.

Section 5.3 No Violation; Consents. The execution and delivery of this Agreement and the consummation of the transactions contemplated hereby will not: (i) violate any applicable law to KKUS or the Assets or the transactions contemplated hereby; (ii) result in the creation or imposition of any encumbrance upon any Asset other than Assumed Liabilities; (iii) require any approval, authorization, consent, license, exemption, filing or registration with any Person, except for such approvals, authorizations, consents, licenses, exemptions, filings or registrations which shall be obtained or made prior to or at the Closing or as otherwise contemplated herein; (iv) conflict with or violate any provisions of the certificate of formation, shareholder agreement or other organizational documents of KKUS; (v) result in the breach of, or a default under any (A) Contract or (B) any other Contract which KKUS is a party, or (vi) result in the breach of, or a default under any order, writ, injunction, judgment or decree to which KKUS is bound or subject, except for, with respect to clauses (v)(B) and (vi) hereof, such breaches or defaults which would not reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect.

Section 5.4 Identification of Assets. KKUS has identified all assets and Assets in Exhibit A, including Intellectual Property and IP Rights, Inventory, Contracts, and Promotional Literature, used or required by it, directly or indirectly, in and for the development, manufacture, distribution, marketing, or sale of the Product in the Territory, as such activities were conducted by KKUS within the one (1) calendar year prior to the Closing.

Section 5.5 Title to Assets. KKUS owns and has the right to transfer its right or interest in all of the Assets and has good, valid and marketable title to all Assets and at the Closing, shall convey each of the Assets free and clear of any encumbrances, other than the Assumed Liabilities. Except as expressly identified as an Assumed Liability, KKUS has not granted rights to any of the Assets to any Third Party. The Assets constitute all of the assets necessary for the development, manufacture, distribution, marketing or sale of the Product in the Territory as such activities were conducted by KKUS as of immediately prior to the Closing.

Section 5.6 Litigation. There is no claim, action, suit, proceeding, investigation, hearing, arbitration, judgment, decree, injunction, rule or order pending or in progress or, to the knowledge of KKUS, threatened against or relating to KKUS, except as expressly identified as an Assumed Liability, (a) in connection with the Assets or the Product, or (b) that challenges, or that may have the effect of preventing, delaying, making illegal, or otherwise interfering with, any of the transactions contemplated by this Agreement, or the ability of KKUS to consummate the transactions contemplated by this Agreement or the ability of Cumberland to make, have made, market, sell or distribute the Product in the Territory. There are no orders, unsatisfied judgments, orders, stipulations, injunctions, decrees, or awards to which any Asset is subject. There are no infringement actions or any other litigation pending or, to KKUS's Knowledge, "KKUS's Knowledge" means the actual knowledge, after reasonable inquiry, of the officers and executives of KKUS.

Section 5.7 Regulatory Matters. KKUS possesses all registrations, permits, licenses, certificates, accreditations and approvals necessary for the development, manufacture, distribution, marketing or sale of the Product in the Territory as such activities were conducted by KKUS as of immediately prior to the Closing and KKUS has not received notice of noncompliance with respect thereto from any Governmental Authority. KKUS has complied with and is in compliance in all material respects with all laws applicable to the development, manufacture, distribution, marketing, or sale of the Product in the Territory as such activities were conducted by KKUS as of immediately prior to the Closing. KKUS is the legal and beneficial owner of the NDA and NDA Approval, which is in full force and effect. KKUS has not received any notice in writing from the FDA, and, to KKUS's Knowledge, there are no facts, which

have, or reasonably should have, led KKUS to believe that the NDA is not currently in good standing with the FDA. KKUS has not, nor, to KKUS's Knowledge, has any of KKUS's employees or contractors been debarred or are deemed subject to debarment pursuant to Section 306 of the United States Federal Food, Drug, and Cosmetic Act or any equivalent applicable law nor are any such Persons the subject of a conviction thereunder. To KKUS's Knowledge, all obligations to conduct post-marketing activities (including with respect to pediatric patients) arising before the Effective Date from any FDA or any other action or notification arising out of or related to the Assets or Product is disclosed on Exhibit B attached hereto.

Section 5.8 Contracts. Schedule A-2 shall list all Contracts which to the best of KKUS's knowledge, KKUS is a party or by which KKUS or any of the Assets are bound relating in any material respect to the Product. KKUS has not received notice that it is in default under, or in breach of, any such Contract and to KKUS's Knowledge, no counterparty has threatened or intends to send such notice. To KKUS's Knowledge, no other party to any such Contract is (with or without the lapse of time or the giving of notice, or both) in material breach or default in any respect thereunder. KKUS has added all known Contracts prior to the Effective Date, to the Data Room established by KKUS for due diligence by Cumberland. Should KKUS locate additional Contracts following the Effective Date, KKUS will promptly send same to Cumberland.

Section 5.9 Treatment of Contracts that Require Third Party Consents to Transfer. If and to the extent that the transfer of the Contracts requires the consent or action of a third party, KKUS and Cumberland shall as soon as permitted by law and reasonably practicable for a period of three (3) months after the date of this Agreement use their reasonable efforts to obtain such consent or action. To the extent (i) that and as long as it is impossible or impracticable to obtain such consent or action or satisfy such condition required for the effective transfer of the Contracts to Cumberland and (ii) permitted under the terms of the Contracts, the Parties will in respect of the internal relationship, use reasonable efforts to treat each other in such a way as if the transfer of the respective Contracts had taken place in accordance with Section 2.1, e.g., use reasonable efforts to enter into such suitable agreements (such as subcontracts, sublicenses or subleases or similar arrangements) so as to (partially) transfer the benefits and burdens arising out of the Contracts to Cumberland. In these cases, KKUS will, in respect of the external relationships, remain the party of the Contracts but will, in respect of the internal relationship between KKUS and Cumberland, continue to hold and be responsible for the relevant Contracts (or the relevant portion thereof) for the account of Cumberland. In particular, (i) any enforcement by KKUS of any right under the Contracts (or the relevant portion thereof) shall be for the account of Cumberland, (ii) KKUS shall manage and attend to the relevant Contracts (or the relevant portion thereof) with due care and in accordance with the instructions of Cumberland and (iii) Cumberland shall indemnify KKUS and its Affiliates against any cost or liability arising from such Contracts (or the relevant portion thereof) as approved in writing by Cumberland or identified as an Assumed Liability. Cumberland will move expeditiously to establish its own commercial relationship with any parties, to the extent it can do so.

Section 5.10 Intellectual Property.

(a) KKUS owns all right, title, and interest in and to the Intellectual Property and IP Rights and has good, valid, and marketable title to all such Intellectual Property and IP Rights.

(b) To KKUS's Knowledge, KKUS has not infringed, nor received notice from any Third Party of a claim that any Intellectual Property or IP Rights of such Third Party would be infringed by the development, manufacture, distribution, marketing, or sale of the Product in the Territory;

(c) The Intellectual Property and IP Rights constitute all of KKUS's Intellectual Property and IP Rights used or relied upon in KKUS's development, manufacture, distribution, marketing, or sale of the Product in the Territory.

Section 5.10. Inventory. All Product and the active pharmaceutical ingredient and drug product included in the Assets was manufactured in accordance with all applicable laws and then current Good Manufacturing Practices pursuant to 21 CFR Parts 210 and 211. All finished drug Product included in the finished goods Inventory of the Assets has been or will be dispositioned, approved, and released by KKUS's quality assurance department.

Section 5.11 Ordinary Course of Business. Prior to the Closing Date, other than as set forth in Schedule A-6, KKUS conducted the Product business with respect to the Territory in the ordinary course and in substantially the same manner as conducted in the period twelve (12) to one (1) month prior to the Closing Date.

Section 5.12 No Brokers. KKUS has not entered into any agreement, arrangement or understanding with any Person which will result in the obligation to pay any finder's fee, brokerage commission or similar payment in connection with the transactions contemplated hereby.

ARTICLE VI
REPRESENTATIONS AND WARRANTIES OF BUYER

Cumberland hereby represents and warrants to KKUS as follows:

Section 6.1 Cumberland's Organization; Good Standing. Cumberland is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its formation. Cumberland has all requisite power and authority to carry on its business as it is currently being conducted. Cumberland is duly qualified to conduct business and is in good standing in every jurisdiction where the nature of the business conducted by it makes such qualification necessary, except where the failure to so qualify or be in good standing would not prevent or materially delay the consummation of the transactions contemplated hereby.

Section 6.2 Authority; Execution and Delivery. Cumberland has the requisite power and authority to enter into this Agreement and to consummate the transactions contemplated hereby. The execution and delivery of this Agreement by Cumberland and the consummation of the transactions contemplated hereby have been duly authorized. This Agreement has been duly executed and delivered by Cumberland and, assuming the due authorization, execution and delivery of this Agreement by KKUS, constitutes the legal, valid and binding obligation of Cumberland, enforceable against Cumberland in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent transfer and other similar laws affecting creditors' rights generally from time to time in effect and to general principles of equity regardless of whether considered in a proceeding in equity or at law.

Section 6.3 No Violations; Consents. The execution and delivery of this Agreement do not, and the consummation of the transactions contemplated hereby and compliance with the terms hereof will not: (a) violate any applicable law applicable to Cumberland or conflict with any material Contract to which Cumberland is a party or by which it is otherwise bound, except for such violations or conflicts which would not materially interfere with Cumberland's performance of its obligations hereunder; or (b) require any approval, authorization, consent, license, exemption, filing or registration with any Person, except for such approvals, authorizations, consents, licenses, exemptions, filings or registrations which have been obtained or made prior to Closing or which, if not obtained or made, would not materially interfere with Cumberland's performance of its obligations hereunder.

Section 6.4 Litigation. There is no suit, claim, action, investigation or proceeding in progress or, to the knowledge of Cumberland, pending or threatened against Cumberland, (a) relating to and adversely affecting this Agreement or the transactions contemplated hereunder or (b) that would materially delay the ability of Cumberland to perform its obligations hereunder.

Section 6.5 No Brokers. Cumberland has not entered into any agreement, arrangement or understanding with any Person which will result in the obligation to pay any finder's fee, brokerage commission or similar payment in connection with the transactions contemplated hereby.

Section 6.6 Consents. No notice to, filing with, authorization of, exemption by, or consent of, any Person, including any applicable Governmental Authority, is required for Cumberland to consummate the transactions contemplated herein, except (a) where the failure to make such filings or notifications, or obtain such consents, approvals, authorizations or permits, would not, individually or in the aggregate, prevent or delay the consummation by Cumberland of the transactions contemplated herein and (b) in connection with the transfer of the NDA.

Section 6.7 Independent Investigation. Cumberland has conducted its own investigation, examination and valuation of the Assets, the Assumed Liabilities and the transactions contemplated by this Agreement. Cumberland has made all inspections and investigations of the Assets and the Assumed Liabilities deemed necessary or desirable by Cumberland. Cumberland is purchasing the Assets, assuming the Assumed Liabilities, and entering into this Agreement based on the results of its inspections and investigations.

ARTICLE VII
CERTAIN COVENANTS AND AGREEMENTS

Section 7.1 Regulatory Commitments.

(a) From and after the NDA Transfer Date, Cumberland shall assume control of, and responsibility for, all obligations to any Governmental Authorities in connection with the NDA and the Product including all pharmacovigilance and medical information services for and in respect of the NDA and the Product.

(b) On the NDA Transfer Date, Cumberland shall assume responsibility for all correspondence and communication with Third Parties, including all Governmental Authorities, relating to the Product, and shall assume all new obligations occurring on or after the NDA Transfer Date with regard to the NDA. Any obligation of KKUS with respect to the NDA that arises prior to the NDA Transfer Date, including but not limited to pharmacovigilance, clinical studies, quality assurance, deficiency letters, corrective action plan agreements, shall remain KKUS's obligation.

(c) Future Manufacturing Campaigns., Cumberland shall register with the FDA to obtain its own labeler code and list with the FDA its own National Drug Code ("NDC") numbers with respect to Product it manufactures Cumberland shall be permitted to sell and distribute finished drug product included in the Assets using KKUS's NDC numbers.

(d) Following the NDA Transfer Date, Cumberland shall, as promptly as practicable, deliver or cause to be delivered to KKUS copies of all confirmations, acknowledgements, and other correspondence from the FDA that the transfer of ownership of the NDA to Cumberland has been completed in full.

Section 7.2 Intellectual Property Commitments. From and after the Closing Date:

(a) Cumberland shall assume control of, and responsibility for, all Assumed Liabilities arising from or related to the Intellectual Property.

(b) Cumberland shall assume responsibility for all prosecution, maintenance, enforcement and defense of the Intellectual Property, including without limitation responsibility for all correspondence and communication with Third Parties, including all Governmental Authorities, relating to the Intellectual Property, if such matter has been identified as an Assumed Liability.

(c) KKUS covenants and agrees that, if Cumberland is prosecuting, contesting or defending any action, claim, action, suit or proceeding by a third party in connection with the Intellectual Property, KKUS shall, and shall use commercially reasonable efforts to cause its Affiliates, if applicable to cooperate with Cumberland and their respective counsel (at the expense of Cumberland) in such prosecution, contest or defense, including making available its personnel and providing such testimony and access to its books and records (including lab notebooks) as shall be reasonably necessary in connection with such prosecution, contest or defense.

Section 7.3 Bulk Transfer Laws. Cumberland hereby waives compliance by KKUS with the provisions of any so-called "bulk transfer law" of any jurisdiction in connection with the sale of the Assets to Cumberland.

Section 7.4 Marketing of Product. From the Closing Date through the NDA Transfer Date, KKUS shall maintain the NDA for the Product in good standing and in full force and effect with the FDA, including making all timely payments of fees and timely filing of all regulatory updates, reports, acknowledgments and other similar submissions.

Section 7.5 Conduct of Business Prior to the Closing. From the date hereof until the earlier of the Closing or the termination of this Agreement in accordance with its terms, except as otherwise provided in this Agreement or consented to in writing by Cumberland (which consent shall not be unreasonably withheld, conditioned or delayed), KKUS shall (x) conduct its business involving the Product in the ordinary course of business and (y) use commercially reasonable efforts to preserve the rights, goodwill and relationships of the KKUS with respect to the Product's customers, licensors, suppliers and distributors. Without limiting the foregoing, from the date hereof until the earlier of the Closing Date or the termination of this Agreement in accordance with its terms, except as otherwise provided in this Agreement or consented to in writing by Cumberland (which consent shall not be unreasonably withheld, conditioned or delayed), KKUS shall not:

(a) waive or release any material right or material claim of arising out of or in connection with such KKUS's business involving the Product other than in the ordinary course of business;

(b) distribute, sell, transfer, lease, license (other than in the ordinary course of business), pledge, encumber or otherwise dispose of any of the Assets;

(c) amend, waive or modify (except in connection with seeking consent to assignment to Cumberland) or consent to the termination of any Contracts, or amend, waive, modify or consent to the termination of KKUS's rights thereunder;

(d) initiate, settle, agree to settle, waive or compromise any claim, action, suit, or proceeding related to the Product;

(e) permit the lapse of the Intellectual Property Rights;

(f) fail to take any action reasonably necessary to protect or maintain the Intellectual Property Rights;

(g) terminate, cancel, permit to lapse, amend, waive or modify any approval or permit with respect to the Assets;

(h) enter into any Contract that would be required to be identified as an Assumed Liability if in existence as of sixty (60) days prior to the Effective Date of this Agreement;

(i) terminate, waive any material provision of, amend or otherwise modify any contract;

(j) change Inventory levels in any manner (other than in the ordinary course of business);

(k) load distribution channels (other than in the ordinary course of business); or

(l) agree or commit to do any of the foregoing.

Section 7.7 Product Special Purpose Financial Statements. Cumberland will determine whether Product special purpose financial statements will be needed or required by on or before the Closing Date. KKUS will provide a draft to Cumberland (after prior consultation with Cumberland and due consideration to any comments of Cumberland) of any such needed or required statements, in the form required by Cumberland, within forty-five (45) days' after the Closing. KKUS will be responsible for their own costs relating to the preparation of the Product special purpose financial statements.

Section 7.8 Commercially Reasonable Efforts. From the date hereof until the earlier of the Closing Date or the termination of this Agreement in accordance with its terms, subject to the terms and

conditions of this Agreement, KKUS and Cumberland shall cooperate, and shall use their commercially reasonable efforts, to (i) take, or cause to be taken, all actions and (ii) do, or cause to be done, all things necessary for it to do, under applicable law to consummate and make effective the transactions contemplated by this Agreement, including all actions and all things necessary for it to (A) comply promptly with all applicable law that may be imposed on it with respect to this Agreement and the transactions contemplated hereby (which actions shall include furnishing all information required by applicable law in connection with approvals of or filings with any Governmental Authority), (B) satisfy the conditions precedent to the obligations of such Party hereto and (C) obtain any consent, authorization, order or approval of, or any exemption by any Governmental Authority or other public or private third party required to be obtained or made by KKUS or Cumberland in connection with the transactions contemplated by this Agreement, in each case, as soon as reasonably practicable following the date hereof; provided, however, that, except as otherwise set forth in this Agreement, no Party shall have any obligation to pay money or make any concessions to obtain such consents. Subject to appropriate confidentiality protections, each Party will furnish to the other Parties such necessary information and reasonable assistance as such other Parties may reasonably request in connection with the foregoing.

Section 7.9 Government Price Reporting.

(a) KKUS will deliver to Cumberland the following government price reporting information for Product following the Closing, transactional detail that is necessary to perform post-Closing government price calculations such as “Average Manufacturer Price” or “AMP” (as defined in 42 U.S.C. § 1396r-8(k)(1) and 42 C.F.R. § 447.500 et seq., as may be amended from time to time), “Best Price” (as defined in 42 U.S.C. § 1396r-8(c)(1)(C) (relating to the definition of Best Price) and 42 C.F.R. § 447.500 et seq., as may be amended from time to time), and the “Non-Federal Average Manufacturer Price” or “Non-FAMP” and “Federal Ceiling Price” or “FCP” (as such terms are defined in 38 U.S.C. § 8126(h)(5) and any applicable agreement between a pharmaceutical manufacturer and the Department of Veterans Affairs to implement the provisions of the Veterans Health Care Act of 1992, 38 U.S.C. § 8126, or the “VA Master Agreement”), including:

(i) with respect to AMP and Best Price: (1) calendar quarter in which baseline AMP was established; (2) baseline AMP; (3) all other baseline product information submitted by KKI to the Centers for Medicare & Medicaid Services (“CMS”) in connection with the Medicaid drug rebate program (including units per package size, market start date, etc.); and (4) transactional data reasonably necessary for Cumberland to calculate AMP and Best Price for the quarters and months (as applicable) beginning with the AMP and Best Price submissions due on or after the Closing Date;

(ii) with respect to the Veterans Health Care Act of 1992: (1) the applicable FCP (as such figure is calculated pursuant to 38 U.S.C. § 8126(a) and the VA Master Agreement); (2) any commercial sales data reasonably necessary to perform quarterly and annual Non-FAMP calculations and (3) any price lists applicable for purposes of sales under any applicable contract with the U.S. Department of Veterans Affairs under Federal Supply Schedule 651B for Drugs, Pharmaceuticals, & Hematology Related Products.

(b) Cumberland acknowledges and agrees that it is responsible for submitting complete and accurate government price reporting calculations for Product, in a timely manner. KKUS will ensure that Cumberland is identified as a delegate in the Medicaid Drug Program System to report AMP and Best Price directly to CMS for the Product and Cumberland will report AMP and Best Price directly to CMS via the Medicaid Drug Program System. In addition, Cumberland will diligent add Product to its Master Agreement, Pharmaceutical Pricing Agreement and Federal Supply Schedule contract with the VA and reported Non-FAMP and FCP directly to the VA for the Product. Given that the HRSA Office of Pharmacy Affairs Information System (“OPAIS”) does not permit delegation, Cumberland will promptly report AMP and Best Price for each quarter to KKUS to facilitate reporting of the 340B Ceiling Price for the Product in OPAIS.

(c) Cumberland shall be responsible for and shall pay to the relevant governmental entity any rebates owed under the Medicaid drug rebate agreement, Medicare Part D Coverage Gap Discount Agreement and any similar government agreements (the “Government Contracts”) with respect to Product utilization after the Closing Date as set forth in Exhibit C Transition Activities.

(d) Cumberland shall be obligated to honor KKUS calculated 340B Ceiling Price for all 340B Covered Entities as well as the Federal Ceiling Price for the “Big Four” (Coast Guard, Department of Defense, Department of Veterans Affairs and the Public Health Service) as well as any other entities entitled to purchase of the Federal Supply Schedule at the Federal Ceiling Price or other discounted price applicable under a contract with the U.S. Department of Veterans Affairs under Federal Supply Schedule 651B for Drugs, Pharmaceuticals, & Hematology Related Products after the Closing Date.

(e) KKUS will cooperate with Cumberland and assist and provide any other available information required for compliance with government reporting, which may include information needed from pre-close periods.

Section 7.10 Regulatory Matters.

(a) KKUS shall use commercially reasonable efforts to assign to Cumberland as of the Closing Date of KKUS’s right, title, and interest existing in and to the approvals and permits of Governmental Authorities necessary for the development, manufacture, distribution, marketing, or sale of the Product in the Territory, with the exception of the NDA and the IND, that are freely transferable, and Cumberland shall assume such right, title, obligations and interest under said approvals and permits.

(b) Cumberland and KKUS shall promptly give written notice to the other upon becoming aware of any action by, or notification or other information which it receives (directly or indirectly) from, any Governmental Authority in the Territory (together with copies of correspondence related thereto), which (A) raises any material concerns regarding the safety or efficacy of the Product, (B) which indicates or suggests a reasonably likely potential material liability for either party to third parties arising in connection with the Product, or (C) which indicates a reasonable potential for a need to initiate a recall, market withdrawal or similar action; in each case with respect to the Product manufactured or sold by KKUS on or prior to the Closing Date.

Section 7.11 No Negotiation. Between the date hereof and the Closing Date or the termination of this Agreement in accordance with its terms, KKUS shall not, and shall not permit any of its Affiliates or representatives to, directly or indirectly, solicit, initiate, encourage or entertain any inquiries or proposals, discuss or negotiate with, provide any information to, consider the merits of any inquires or proposals from any Person (other than Cumberland) to enter into any contract or instrument relating to any transaction involving, in whole or in part, the Assets or the Product or that would otherwise compromise the ability of KKUS to consummate the transactions contemplated by this Agreement. KKUS shall promptly advise Cumberland, orally and in writing, of any such inquiry or proposal received from a third party. KKUS agrees that the rights and remedies for noncompliance with this Section shall include having such provision specifically enforced by a court having equity jurisdiction, it being acknowledged that any such breach or threatened breach may cause irreparable injury to Cumberland and that money damages will not provide an adequate remedy to Cumberland.

Section 7.12 Notice of Certain Events.

(a) From the date hereof until the earlier of the Closing Date or the termination of this Agreement in accordance with its terms, KKUS shall promptly notify Cumberland of any of the following:

(i) any written notice from any Person alleging that the consent of such Person is or may be required in connection with the transactions contemplated by this Agreement, if the failure to obtain such consent would, individually or in the aggregate, reasonably be expected to be materially adverse to consummation of the transactions contemplated by this Agreement; and

(ii) any damage or destruction by fire or other casualty of any material Asset or part thereof or the occurrence of any Material Adverse Effect; provided, however, that the delivery of any notice pursuant to this Section shall not limit or otherwise affect the remedies available hereunder to Cumberland.

(b) Each Party shall promptly notify the others of any written notice communication by such Party from any Governmental Authority in connection with the transactions contemplated by this Agreement.

ARTICLE VIII CONDITIONS TO CLOSING

Section 8.1 Conditions to Obligations of Cumberland. The obligations of Cumberland to consummate the transactions contemplated by this Agreement shall be subject to the fulfillment or Cumberland's waiver, at or prior to the Closing, of each of the following conditions:

(a) The representations and warranties of KKUS contained in Article V shall be true and correct in all material respects (except as qualified by materiality or Material Adverse Effect, in which case they shall be true and correct in all respects) as of the Closing Date with the same effect as though made at and as of such date (except those representations and warranties that address matters only as of a specified date, which shall be true and correct in all material respects as of that specified date).

(b) KKUS shall have duly performed and complied in all material respects with all agreements, covenants and conditions required by this Agreement to be performed or complied with prior to or on the Closing Date.

(c) KKUS shall have complied with each condition set forth in Article IV hereof and shall have delivered the items set forth therein, in each case as applicable to KKUS.

(d) There shall not have occurred any Material Adverse Effect.

(e) There shall not be any applicable law in effect prohibiting the consummation of the transactions contemplated by this Agreement or any claim, action, suit, proceeding, investigation, hearing, arbitration, judgment, decree, injunction pending before any Governmental Authority that, if adversely determined, would prohibit the consummation of the transactions contemplated by this Agreement.

Section 8.2 Conditions to Obligations of KKUS. The obligations of KKUS to consummate the transactions contemplated by this Agreement shall be subject to the fulfillment or KKUS's waiver, at or prior to the Closing, of each of the following conditions:

(a) The representations and warranties of Cumberland contained in Article VI shall be true and correct in all material respects (except as qualified by materiality or Material Adverse Effect, in which case they shall be true and correct in all respects) as of the Closing Date with the same effect as though made at and as of such date (except those representations and warranties that address matters only as of a specified date, which shall be true and correct in all respects as of that specified date).

(b) Cumberland shall have duly performed and complied in all material respects with all agreements, covenants and conditions required by this Agreement to be performed or complied with by it prior to or on the Closing Date.

(c) Cumberland shall have complied with each condition set forth in Article IV hereof and shall have delivered the items set forth therein, in each case as applicable to Cumberland.

(d) There shall not be any applicable law in effect prohibiting the consummation of the transactions contemplated by this Agreement or any claim, action, suit, proceeding, investigation, hearing, arbitration, judgment, decree, injunction pending before any Governmental Authority that, if adversely determined, would prohibit the consummation of the transactions contemplated by this Agreement.

ARTICLE IX
INDEMNIFICATION

Section 9.1 Survival. All representations and warranties of KKUS and Cumberland contained herein or made pursuant hereto shall survive the Closing Date.

Section 9.2 Indemnification by KKUS. After the Closing Date, KKUS hereby agrees to indemnify and hold harmless Cumberland and its Affiliates and their respective officers, directors, stockholders, employees and agents (the "Cumberland Indemnified Parties") against, and agrees to hold them harmless from, any Loss to the extent such Loss arises from or in connection with the following:

(a) the ownership and operation of the Assets by KKUS and the development, manufacture, distribution, market or sale of Product by KKUS through the Closing Date (in each instance including actions taken by licensees of KKUS or its Affiliates);

(b) any breach by KKUS of any representation or warranty or any of its covenants, agreements, or obligations contained in this Agreement;

Section 9.3 Indemnification by Cumberland. From and after the Closing Date, Cumberland hereby agrees to indemnify and hold harmless KKUS and its respective Affiliates and their respective officers, directors, and employees (the "KKUS Indemnified Parties") against, and agrees to hold them harmless from, any Loss to the extent such Loss arises from or in connection with the following:

(a) the ownership and operation of the Assets by Cumberland and the development, manufacture, distribution, market and sale of Product by Cumberland after the Closing Date;

(b) any breach by Cumberland of any representation or warranty or any of its covenants, agreements, or obligations contained in this Agreement;

(c) any failure by Cumberland to pay, perform or discharge when due, an Assumed Liability.

Section 9.4 Indemnification Notice. Each Indemnified Party shall deliver to the Indemnifying Party, within thirty (30) Business Days' after the Indemnified Party's discovery of matters giving rise to a Loss, all information and documentation reasonably requested by the Indemnifying Party with respect to such Loss. The failure to give timely notification of a Loss shall not affect the indemnification provided hereunder except to the extent the Indemnifying Party shall have been actually prejudiced as a result of such failure.

ARTICLE X
TERMINATION

Section 10.1 Termination. This Agreement may be terminated at any time prior to the Closing:

(a) by the mutual written consent of KKUS and Cumberland;

(b) by Cumberland or KKUS in the event that there shall be any applicable law that makes consummation of the transactions contemplated by this Agreement illegal or otherwise prohibited.

Section 10.2 Effect of Termination. In the event of the termination of this Agreement in accordance with this Article, this Agreement shall be void and there shall be no liability on the part of any party hereto except:

(a) as set forth in this Article X and Article XI;

(b) that nothing herein shall relieve any party hereto from liability for any willful misconduct or fraud with scienter.

ARTICLE XI
GENERAL PROVISIONS

Section 11.1 No Consequential Damages. EXCEPT IN THE CASE OF FRAUD WITH SCIENTER OR WILLFUL MISCONDUCT, NO PARTY TO THIS AGREEMENT SHALL BE LIABLE TO OR OTHERWISE RESPONSIBLE TO ANY OTHER PARTY HERETO OR ANY AFFILIATE OF ANY OTHER PARTY HERETO FOR (I) ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, (II) ANY AMOUNT CALCULATED BASED UPON ANY MULTIPLE OF EARNINGS, BOOK VALUE OR CASH FLOW, OR DIMINUTION IN VALUE, (III) ANY INDIRECT DAMAGES (INCLUDING BUSINESS INTERRUPTION, LOSS OF FUTURE REVENUE, INCOME OR PROFITS OR LOSS OF BUSINESS REPUTATION OR OPPORTUNITY), WHETHER OR NOT THE POSSIBILITY OF SUCH DAMAGES HAS BEEN DISCLOSED TO THE OTHER PARTY IN ADVANCE OR COULD HAVE BEEN REASONABLY FORESEEN BY SUCH OTHER PARTY.

Section 11.2 Expenses. Except as otherwise specified in this Agreement, all costs and expenses (including fees and disbursements of counsel, financial advisors and accountants) incurred in connection with this Agreement and the transactions contemplated hereby will be paid by the Party incurring such costs and expenses, whether or not the Closing will have occurred.

Section 11.3 Confidential Information.

(a) Each Party shall keep confidential, and shall use reasonable efforts to cause its respective directors, officers, employees, agents and representatives to keep confidential, all information relating to this Agreement, the Assets and the Assumed Liabilities (the "Confidential Information"), except (i) as may be required to comply with the requirements of applicable laws, and the rules and regulations of each stock exchange upon which the securities of the Parties are listed (including, for the avoidance of doubt, filings required by the Securities Exchange Act of 1934 [the "Exchange Act"] and the Securities Act of 1933, each as amended), (ii) as necessary to defend or prosecute any indemnification claim or any litigation or dispute, (iii) as required by the transition and license obligations hereunder, or (iv) for information that is lawfully made available to the public on the Closing Date, or thereafter becomes available to the public other than as a result of a breach of this Section. The covenants of each Party in this Section 11.3 shall terminate after the Product is no longer marketed in the Territory by Cumberland. Each Party shall treat, and will cause its Affiliates and its representatives and the representatives of its Affiliates to treat, the Confidential Information as confidential, using the same degree of care as KKUS normally employs to safeguard its own confidential information from unauthorized use or disclosure, but in no event less than a reasonable degree of care.

(b) In the event either Party is required to disclose any of the Confidential Information pursuant to any Governmental Authority or judicial, administrative order, subpoena, discovery request, regulatory request or similar method, the disclosing Party shall promptly notify the other in writing of such demand for disclosure so that the non-disclosing Party, at its sole expense, may seek to make such disclosure subject to a protective order or other appropriate remedy to preserve the confidentiality of the Confidential Information. Each Party will cooperate in all reasonable respects, in connection with any actions to be taken for the foregoing purpose. In the case of such compelled disclosure, the disclosing Party shall disclose Confidential Information only to the extent necessary to satisfy such compelled disclosure herein described.

(c) Notwithstanding anything herein to the contrary, following the Closing, KKUS and Cumberland shall cooperate in good faith to agree in writing on the method and content of the notifications to partners, customers and suppliers involved in the manufacture, marketing, and sale of the Product prior to the Closing.

Section 11.4 Amendments and Waivers. This Agreement may not be amended except by an instrument in writing signed by authorized signatories on behalf of each Party. By an instrument in writing, Cumberland or KKUS may waive compliance by the other Party with any term or provision of this Agreement that such other Party was or is obligated to comply with or perform.

Section 11.5 Return of Information. If for any reason whatsoever the transactions contemplated by this Agreement are not consummated, Cumberland shall promptly return to KKUS or destroy all books and records furnished by the KKUS and its respective Affiliates, agents, employees, or representatives (including all copies thereof) in accordance with the terms of the confidentiality agreement entered into by the Parties, subject to any document retention expressly permitted thereunder.

Section 11.6 Notices. All notices, requests and other communications hereunder shall be in writing and shall be sent, delivered, or mailed, addressed as follows:

(a) if to Cumberland, to:

Cumberland Pharmaceuticals, Inc.
2525 West End Avenue
Suite 950
Nashville, TN 37203
Telephone: 615-255-0068
Attn: Chief Executive Officer

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

Cumberland Pharmaceuticals, Inc.
2525 West End Avenue
Suite 950
Nashville, TN 37203
Telephone: 615-255-0068
Attn: Corporate Legal Counsel

(b) if to KKUS, to:

Kyowa Kirin, Inc.
135 Route US-202, Suite 6
Bedminster, NJ 07921
Tel: 908-234-1096
Attn: President
KKNAPresident@kyowakirin.com

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

Kyowa Kirin, Inc.
135 Route US-202, Suite 6
Bedminster, NJ 07921
Tel: 908-234-1096
Attn: General Counsel
kkna.legal.b2@kyowakirin.com

Each such notice, request or other communication shall be given by: (i) hand delivery; (ii) certified mail; or (iii) nationally recognized courier service such as FedEx or UPS. Each such notice, request or communication shall be effective when delivered at the address specified in this Section 11.6 (or in accordance with the latest unrevoked direction from the receiving Party).

Section 11.7 Headings. The headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.

Section 11.8 Severability. If any term or other provision of this Agreement is invalid, illegal or incapable of being enforced under any applicable law or public policy, all other terms and provisions of this Agreement shall nevertheless remain in full force and effect so long as the economic or legal substance of the transactions contemplated hereby is not affected in any manner materially adverse to any Party. Upon such determination that any term or other provision is invalid, illegal or incapable of being enforced, the Parties shall negotiate in good faith to modify this Agreement so as to effect the original intent of the Parties hereto as closely as possible in an acceptable manner in order that the transactions contemplated hereby are consummated as originally contemplated to the greatest extent possible.

Section 11.9 Counterparts. This Agreement may be executed by email in portable document format and in one or more counterparts, all of which shall be considered one and the same agreement and shall become effective when one or more counterparts have been signed by each Party and delivered by each Party to the other Party, it being understood that all Parties hereto need not sign the same counterpart.

Section 11.10 Entire Agreement. This Agreement, together with the Schedules and Exhibits attached hereto, constitute the entire agreement and supersede all prior agreements and understandings, both written and oral, between or among the Parties with respect to the subject matter hereof. The Exhibits, Schedules, certificates, and notices specifically referred to herein, and delivered pursuant hereto, are an integral part of this Agreement.

Section 11.11 Third Party Beneficiaries. Except as specifically provided herein, this Agreement is intended solely for the benefit of each Party and their respective successors or permitted assigns and it is not intended to confer upon any Person other than the Parties any rights or remedies hereunder.

Section 11.12 Governing Law. This Agreement will be deemed to have been made in the State of New York and its form, execution, validity, construction and effect will be determined in accordance with the laws of the State of New York, without giving effect to the principles of conflicts of law thereof.

Section 11.13 Dispute Resolution. Any dispute arising out of or relating to this Agreement or the breach thereof, including any matter of Specific Performance pursuant to Section 11.14, shall be resolved in the follow order:

- (a) by submission of the dispute to the Joint Steering Committee, and if not resolved within ten (10) days' of submission,
- (b) by submission of the dispute to resolution between each Party's CEOs, and if not resolved within ten (10) days' of submission,
- (c) shall be finally resolved by binding arbitration under the Rules of American Arbitration Association, and judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction. The arbitration will be conducted in the English language. There shall be one (1) arbitrator, mutually selected and mutually agreed to by the Parties, and named in accordance with such Rules. The place of arbitration shall be New York, New York.

Section 11.14 Specific Performance. The Parties agree that irreparable damage may occur if any provision of this Agreement were not performed in accordance with the terms hereof or thereof and that the Parties may be entitled to seek a temporary injunction or injunctions to prevent breaches of this Agreement or to enforce specifically the performance of the terms and provisions hereof, or to seek a permanent injunction in addition to any other remedy to which they are entitled at law or in equity.

Section 11.15 Waiver. No waiver by either Party of any term or condition of this Agreement, in any one or more instances, shall be deemed to be or construed as a waiver of the same or any other term or condition of this Agreement on any future occasion.

Section 11.16 Assignment.

(a) No Party may assign any or all of its rights or obligations under this Agreement without the other Party's prior written consent; provided, however, that (i) either Cumberland or KKUS may assign any or all of its rights or obligations under this Agreement to an Affiliate of such Party, and (ii) either Cumberland or KKUS may assign all of its rights or obligations under this Agreement to a Third Party to which such Party has sold all or substantially all of its assets relating to this Agreement.

(b) In the event that a Party assigns any of its rights and obligations hereunder to an Affiliate or Third Party, the assigning Party shall, at the request of the non-assigning Party, enter into, or cause such Third Party to enter into, such supplemental agreements pursuant to which such Third Party will expressly assume all of the obligations of the assigning Party hereunder. Any assignment to an Affiliate of a Party shall not release the assigning or transferring Party of its obligations hereunder. In the event that a Party assigns any of its rights and obligations hereunder to a Person, firm or other entity that qualifies as an Affiliate hereunder and during the term of this Agreement such Person, firm or other entity ceases to qualify as an Affiliate hereunder, such Person, firm or other entity shall promptly, with written notice to the other Party, assign back to such Party any of its rights and obligations hereunder.

(c) This Agreement shall be binding upon and inure to the benefit of the Parties, and their respective successors and permitted assigns.

Section 11.17 Advice of Counsel. The language in all parts of this Agreement shall be deemed to be the language mutually chosen by the Parties. The Parties hereto and their counsel have cooperated in the drafting and preparation of this Agreement, and this Agreement therefore shall not be construed against any Party by virtue of its role as the drafter thereof. No drafts of this Agreement or any other similar or related document exchanged by the Parties prior to the Closing Date shall be offered by a Party, nor shall any draft be admissible in any proceeding, to explain or construe this Agreement or for any other purpose.

Section 11.18 Press Release. Following the Closing Date, the Parties each intend to issue a press release announcing the signing of this Agreement and have shared drafts of those releases with each other. Notwithstanding anything herein to the contrary, each of the Parties hereby agrees with the other Party that it will consult with and provide each other the opportunity to review and comment upon any press release or other public statement or comment prior to the issuance of such press release or other public statement or comment relating to this Agreement or the transactions contemplated herein and shall not issue any press release or other public statement or comment without the prior written consent of the other Parties, except (i) as may be required to comply with the requirements of any applicable laws, and the rules and regulations of each stock exchange upon which the securities of one of the Parties is listed or (ii) as may be consistent with previous press releases or other public statements or comments relating to this Agreement or the transactions contemplated herein approved by the Parties.

Signatures on Following Page

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be signed by their respective representatives thereunto duly authorized, all as of the date hereof.

Kyowa Kirin, Inc.

By: /s/ Gary Zieziula

Name: Gary Zieziula

Title: Region President

Cumberland Pharmaceuticals Inc.

By: /s/ A.J. Kazimi

Name: A.J. Kazimi

Title: Chief Executive Officer

List of Omitted Exhibits and Schedules

EXHIBIT A
Assets

EXHIBIT A
Schedule A-1
Sancuso Product

Schedule A-2
List of Contracts

Schedule A-3
Closing Inventory

Schedule A-4
United States Intellectual Property Rights

Schedule A-5
Marketing and Promotional Literature

Schedule A-6
Non-ordinary Course of Business Items

EXHIBIT B
ASSUMED LIABILITIES

EXHIBIT C
TRANSITION SERVICES AND ACTIVITIES



CUMBERLAND PHARMACEUTICALS ACQUIRES SANCUSO® FROM KYOWA KIRIN NORTH AMERICA

Nashville-based pharmaceutical company will acquire U.S. rights from Japan-based Kyowa Kirin

SANCUSO® is an established, FDA-Approved Oncology Supportive Care Medicine

NASHVILLE, Tennessee and BEDMINSTER, New Jersey (January 4, 2022) – Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX), a specialty pharmaceutical company, announced today that it has entered into and closed on a definitive agreement to acquire the FDA-approved oncology-supportive care medicine SANCUSO® (*granisetron transdermal patch*), from **Kyowa Kirin, Inc.** the U.S. affiliate of Japan-based Kyowa Kirin Co., Ltd. (Kyowa Kirin, TSE: 4151), a global specialty pharmaceutical company focused on discovering and delivering novel medicines.

SANCUSO is the first and only FDA-approved prescription patch for the prevention of nausea and vomiting in patients receiving certain types of chemotherapy treatment. The active drug in SANCUSO, granisetron, slowly dissolves in the thin layer of adhesive that sticks to the patient's skin and is released into their bloodstream over several days, working continuously to prevent chemotherapy-induced nausea and vomiting (CINV). It is applied 24 to 48 hours before receiving chemotherapy and can prevent CINV for up to five consecutive days. Alternative oral treatments must be taken several times (day and night) to deliver the same therapeutic doses.

“In 2020 there were nearly two million new cases of cancer in the U.S. and each year over half a million Americans undergo chemotherapy, with many suffering from the side effects of their treatment. With SANCUSO, patients are given a simple, easy-to-apply preventative solution that doesn't require swallowing any pills – which can be difficult for patients experiencing nausea,” said A.J. Kazimi, chief executive officer at Cumberland Pharmaceuticals. “We are honored to take responsibility for the brand and introduce it through our commercial organization, ensuring that it is delivered to the patients who need it.”

Under the terms of the agreement, Cumberland will acquire U.S. rights to SANCUSO and will assume full commercial responsibility for the product – including its marketing, promotion, distribution, manufacturing and medical support activities. Net sales of the brand in the U.S. were over \$14 million in 2020. The financial terms of the acquisition include a \$13.5 million payment to Kyowa Kirin upon closing, up to \$3.5 million in milestones and tiered royalties of up to 10% on U.S. net product sales. Kyowa Kirin will retain international rights, continuing to deliver the product to address oncology patients' needs throughout the rest of the world.

“Since its launch in 2008, we have established SANCUSO as an important supportive therapeutic solution for oncology patients across the country,” said Gary Zieziula, president of Kyowa Kirin North America. “We believe that Cumberland is well positioned to optimize the value of the brand and ensure that this unique product continues to deliver important therapeutic benefits to oncology patients.”

About Cumberland Pharmaceuticals

Cumberland Pharmaceuticals Inc. is a specialty pharmaceutical company focused on the delivery of high-quality, prescription brands designed to improve patient care. The Company develops, acquires, and commercializes products for the hospital acute care, gastroenterology and rheumatology market segments. The Company's portfolio now includes eight FDA-approved brands.

The Company also has a series of Phase II clinical programs underway evaluating its ifetroban product candidate in patients with cardiomyopathy associated with Duchenne Muscular Dystrophy (“DMD”), Systemic Sclerosis (“SSc”), and Aspirin-Exacerbated Respiratory Disease (“AERD”).

More information can be found on the Company's website at www.cumberlandpharma.com.

About Kyowa Kirin

Kyowa Kirin strives to create and deliver novel medicines with life-changing value. As a Japan-based global specialty pharmaceutical company with a more than 70-year heritage, the company applies cutting-edge science, including expertise in antibody research and engineering, to address the needs of patients across multiple therapeutic areas such as nephrology, oncology, immunology/allergy and neurology. Across its four regions – Japan, Asia Pacific, North America and EMEA/International – Kyowa Kirin focuses on its purpose, to make people smile, and is united by its shared values of commitment to life, teamwork, innovation and integrity.

Learn more about the Company at www.kyowakirin.com.

About SANCUSO®

SANCUSO is the only skin patch approved by the U.S. Food and Drug Administration for the prevention of chemotherapy-induced nausea and vomiting (CINV) in patients receiving moderately and/or highly emetogenic chemotherapy. When applied 24 to 48 hours before receiving chemotherapy, the SANCUSO patch slowly and continuously releases the medicine contained in the adhesive through clean and intact skin areas into the patient's bloodstream. It can be worn for up to seven days in a row for chemotherapy regimens of up to five consecutive days.

Learn more at www.sancuso.com.

Forward-Looking Statements

This press release contains forward-looking statements, which are subject to certain risks and reflect the companies' current views on future events based on what it believes are reasonable assumptions. No assurance can be given that these events will occur. As with any business, all phases of the companies' operations are subject to factors outside of its control, and any one or combination of these factors could materially affect results of operations. There can be no assurance that anticipated results associated with the brand will be realized or that they will have the expected effects. Readers are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date hereof. The companies do not undertake any obligation to publicly revise these statements to reflect events after the date hereof. Investors should refer to filings with the government securities agencies for more information, including the risk factors associated an investment in each company.

Please see SANCUSO Indication and Important Safety Information below

Indication

SANCUSO® (granisetron transdermal system) is indicated for the prevention of nausea and vomiting in adults receiving moderately and/or highly emetogenic chemotherapy regimens of up to five consecutive days.

Important Safety Information

Contraindications:

SANCUSO is contraindicated in patients with known hypersensitivity to granisetron or to any of the components of the transdermal system.

Warnings and Precautions:

Progressive Ileus and Gastric Distention: SANCUSO may mask a progressive ileus and/or gastric distention. This should be particularly considered before use of SANCUSO in patients who have had recent abdominal surgery. Monitor for decreased bowel activity, particularly in patients with risk factors for gastrointestinal obstruction.

Serotonin Syndrome: The development of serotonin syndrome has been reported with 5-HT₃ receptor antagonists. Patients should be monitored for the emergence of serotonin syndrome, especially with concomitant use of SANCUSO and other serotonergic drugs. If symptoms of serotonin syndrome occur, discontinue SANCUSO and initiate supportive treatment. Patients should be informed of the increased risk of serotonin syndrome, especially if SANCUSO is used concomitantly with other serotonergic drugs.

Skin Reactions: In clinical trials with SANCUSO, application site reactions were reported that were generally mild in intensity and did not lead to discontinuation of use. The incidence of reactions was comparable with placebo. If severe reactions, or a generalized skin reaction occur (e.g., allergic rash, including erythematous, macular, papular rash or pruritus), remove the SANCUSO transdermal system.

Increased Drug Exposure with Use of External Heat Sources: Prolonged exposure to heat results in increasing plasma concentrations of granisetron during the period of heat exposure. Do not apply a heat pad or heat lamp over or in the vicinity of the SANCUSO transdermal system and avoid extended exposure to heat.

Phototoxicity with Ultraviolet Light Exposure: Granisetron may be affected by direct natural or artificial sunlight, including sunlamps. An in vitro study using Chinese hamster ovary cells suggests that granisetron has the potential for photogenotoxicity. To avoid a potential skin reaction, advise patients to cover the application site of the transdermal system with clothing if there is a risk of exposure to direct natural or artificial sunlight throughout the period of wear and for 10 days following its removal.

Adverse Reactions:

The most common adverse reaction ($\geq 3\%$) is constipation.

You are encouraged to report suspected adverse reactions to Kyowa Kirin, Inc. at 1-800-Sancuso or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please click [here](#) for full U.S. prescribing information.

SOURCE: Cumberland Pharmaceuticals Inc. and Kyowa Kirin Inc.

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Cumberland Contact: Kyowa Kirin Contact: Media Contact:

Shayla Simpson Lauren Walrath Molly Aggas
Cumberland Pharmaceuticals Kyowa Kirin North America Dalton Agency
(615) 255-0068 (646) 526-4454 (704) 641-6641

lauren.walrath.g4@kyowakirin.com maggas@daltonagency.com