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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

December 12, 2022 (December 6, 2022)
Date of Report (date of earliest event reported)

CUMBERLAND PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

Tennessee	**001-33637**	**62-1765329**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

1600 West End Avenue, Suite 1300 Nashville, Tennessee 37203
(Address of Principal Executive Offices)
(615) 255-0068
Registrant's telephone number, including area code

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

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

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

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, 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 8.01 Other Events

On December 6, 2022, Cumberland Pharmaceuticals Inc. (“Cumberland”) received notification from Kyowa Kirin, Inc. (“Kyowa Kirin”) that the U.S. Food and Drug Administration ("FDA") approved a supplemental new drug application (“sNDA”) associated with a new site at Kindeva Drug Delivery L.P. (“Kindeva”), for the manufacturing and primary packaging of Cumberland’s Sancuso® brand.

In January 2022, Cumberland acquired the U.S. rights to Sancuso® from Kyowa Kirin and assumed full commercial responsibility for the product in the U.S. – including its marketing, promotion, distribution, manufacturing and medical support activities. In March 2019, Kyowa Kirin submitted a Prior Approval sNDA for the new Kindeva manufacturing site. In June 2019, Kyowa Kirin received a complete response letter from the FDA regarding the sNDA submission which included a request for clinical information. On August 12, 2022, Kyowa Kirin submitted an amendment to the sNDA that included the requested information. After the amendment was reviewed by the FDA, approval was granted.

Based on the terms of the Sancuso acquisition agreement, Cumberland will provide a $1 million milestone payment to Kyowa Kirin who was responsible for developing the needed clinical and manufacturing data, preparing the submission and securing the FDA approval.

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.

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.

Cumberland Pharmaceuticals Inc.

Dated: December 12, 2022

By: */s/ John Hamm*
John Hamm
Chief Financial Officer