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

November 4, 2024 (November 4, 2024)
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

In April 2023, we announced that we expected that our Caldolor product would be eligible for separate Medicare reimbursement under the *Non-Opioids Prevent Addiction in the Nation Act* (the "NOPAIN Act"), which was enacted as part of the Consolidated Appropriations Act of 2023.

This Act requires the Centers for Medicare & Medicaid Services ("CMS") to provide separate reimbursement for non-opioid products that are used to manage pain during surgeries conducted in hospital outpatient departments or in ambulatory surgical centers. The NOPAIN Act applies, in part, to products that are indicated to provide analgesia without acting upon the body's opioid receptors. The reimbursement for non-opioid pain alternatives under the NOPAIN Act will apply to those products that are furnished between January 1, 2025, and January 1, 2028.

Cumberland submitted comments to CMS in July 2023 and July 2024, arguing, among other things, that Caldolor meets the statutory requirements for separate payment under the NOPAIN Act because the U.S. Food and Drug Administration ("FDA") approved Caldolor for a general acute pain indication that encompasses use for the reduction of postoperative pain based on clinical studies in patients with postoperative pain.

On November 1, 2024, CMS announced a list of products for separate payment under the NOPAIN Act through their Calendar Year 2025 *Medicare Outpatient Prospective Payment System* ("OPPS") Ruling. The list does not include Caldolor. CMS concluded that Caldolor and certain other products do not qualify for separate payment under the NOPAIN Act because "there is no mention of post-operative or post-surgical use in the FDA-approved indications."

The Company was surprised and disappointed with this determination, as the majority of Caldolor's use is associated with surgery and the FDA approval of the product's pain indication was based on studies of patients with post-surgical pain.

Furthermore, CMS's November 1 list of products eligible for separate payment under the NOPAIN Act does not appear to add any new pharmaceuticals. Cumberland does not believe that CMS's determination regarding Caldolor is consistent with the intent of the NOPAIN legislation.

We are evaluating our potential options, and next initiatives for continuing to seek separate payment for Caldolor.

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.

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: November 4, 2024

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