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

May 16, 2023 (May 15, 2023)
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 May 15, 2023, Cumberland Pharmaceuticals Inc. ("Cumberland" or the "Company") announced that the U.S. Food and Drug Administration (FDA) has approved expanded labeling for Caldolor®, an intravenously delivered formulation of ibuprofen, to now include use in infants. The non-narcotic agent may now be administered for the treatment of pain and fever in patients three months to six months of age.

The newly FDA-approved label includes information regarding the product's indications and usage, appropriate patient populations, clinical study results, potential side effects, patient safety details, and instructions for use in these young children.

Caldolor is now approved by the U.S. Food and Drug Administration (FDA) for use in adults and pediatric patients three months and older, for the management of mild to moderate pain as a sole therapy, and for the management of moderate to severe pain as an adjunct to an opioid. A series of published clinical studies have demonstrated that Caldolor significantly reduces patient pain, while also significantly reducing patients' need for opioids.

Full prescribing and safety information can be found at the brand's website www.caldolor.com.

A copy of the release is furnished as Exhibit 99.1.

Exhibit No.	Description
99.1	Press release dated May 15, 2023

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: May 16, 2023

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

CALDOLOR® NOW FDA APPROVED
FOR TREATMENT OF FEVER & PAIN IN INFANTS

Caldolor® is the only injectable non-opioid approved for treating pain in infants

NASHVILLE, TN (Monday, May 15, 2023) – Cumberland Pharmaceuticals Inc. **(NASDAQ: CPIX),** a specialty pharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has approved expanded labeling for Caldolor®, an intravenously delivered formulation of ibuprofen, to now include use in infants. The non-narcotic agent may now be administered for the treatment of pain and fever in patients three months to six months of age.

The newly FDA-approved label includes information regarding the product's indications and usage, appropriate patient populations, clinical study results, potential side effects, patient safety details, and instructions for use in these young children.

To support this expanded use of Caldolor, Cumberland sponsored a multi-center study in 21 hospitalized infants. All but one patient was treated with a single dose of the product.

The safety and efficacy of Caldolor has now been established for the treatment of pain and fever in pediatric patients aged 3 months and older. Use of Caldolor for these indications is supported by evidence from one adequate and controlled open label study in infants, along with additional safety data from four studies in 164 pediatric patients, supportive pediatric data from other approved ibuprofen products, and evidence from adequate and well-controlled studies in adults.

Importantly with this newly approved labeling, Caldolor is the only non-opioid product approved to treat pain in infants that is delivered through injection. Ketorolac and meloxicam are not approved for use in children, as the safety and efficacy of those drugs have not been established for pediatric patients. Acetaminophen injection is not approved for treating pain in children less than 2 years of age, as the safety and efficacy of that drug has not been established for treating pain in those pediatric patients.

"We are delighted to provide Caldolor for these youngest of patients," said A.J. Kazimi, chief executive officer of Cumberland Pharmaceuticals. "We believe that this approval for the product's use in infants speaks to Caldolor's favorable safety profile for use in a growing number of patient populations."

Cumberland previously announced FDA approval for use in pre-operative administration. The non-narcotic pain reliever may be administered just prior to surgery, which enables patients to wake up from their procedures in significantly less pain. Caldolor presents a potentially safer alternative to opioids for controlling pain, as the FDA has recently required new safety warnings on the use of opioids.

In addition, the Company recently reported that it expects Caldolor will be eligible for special 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.